

IN THE UNITED STATES DISTRICT COURT FOR THE  
SOUTHERN DISTRICT OF WEST VIRGINIA, HUNTINGTON DIVISION  
BEFORE THE HONORABLE ROBERT C. CHAMBERS, JUDGE

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CLAUDE R. KNIGHT and CLAUDIA  
STEVENS, individually and as  
personal representatives of the  
Estate of BETTY ERLINE KNIGHT,  
deceased,

Plaintiffs,

vs.

No. 3:15-CV-06424

BOEHRINGER INGELHEIM  
PHARMACEUTICALS, INC.,

Volume 7  
Pages 1101 through 1439

Defendant.

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REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL

MONDAY, OCTOBER 15, 2018, 9:00 A.M.

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(Appearances continued next page...)

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1 HUNTINGTON, WEST VIRGINIA

2 MONDAY, OCTOBER 15, 2018, 9:04 A.M.

3 (Proceedings held in the conference room, jury not  
4 present.)

5 THE COURT: Good morning.

6 All right. So first I wanted to take up the summary  
7 presentation that the plaintiffs have offered. I've read  
8 the plaintiffs' submission and the defendant's submission.  
9 I don't think there's a whole lot of significant issue. I'm  
10 prepared to just go through and tell you what I think.

11 MR. CHILDERS: Sure.

12 THE COURT: You can -- so we'll just use the  
13 defendant's response where they state their objections to  
14 the amended version of plaintiffs' presentation.

15 As I understand it, the first one is on Page 4, slide  
16 4. This was an objection to the final statement concerning  
17 Dr. MacFarland. As I read it, the defendant merely wants to  
18 make clear that in the statement referring to the knowledge  
19 that Dr. MacFarland had about Pradaxa at the time it was  
20 first prescribed to her, the plaintiff wanted to leave the  
21 word "first" out.

22 MR. CHILDERS: I think you have it the other way  
23 around, Your Honor.

24 THE COURT: Okay. So what I'm reading is the  
25 defendant's response.

1 MR. CHILDERS: I'm sorry. I'm sorry. You are  
2 right.

3 THE COURT: Yeah, all right. I want to make sure  
4 I'm properly oriented to time and space this morning.

5 So I agree with the defendant. The only issue about  
6 her is when it was first prescribed. She wasn't providing  
7 testimony about any of the later ones.

8 The second, the defendant objects to the reference to  
9 Mrs. Knight's health issues. I agree with the plaintiff on  
10 this. "Issues" to me is a broader term. It encapsulates a  
11 lot of her conditions. She had more than one health  
12 problem. So I'm inclined to leave it as plaintiff has  
13 proposed it.

14 Number 6, Dr. Van Ryn. The defendant objected to the  
15 very last statement, said it was redundant. I disagree. I  
16 think that the statements go hand-in-hand because I think  
17 the first statement to which there's no objection is just  
18 summarizing that she described generally the relationship  
19 between patients, Pradaxa exposure, and bleeding risk and  
20 then concluded that increased blood levels of Pradaxa  
21 increase bleeding risk. I think it's an accurate statement  
22 of her testimony.

23 Dr. Ashhab. The defendant objects to the reference to  
24 the fact that he treats patients from the Charleston area.  
25 I think it's fair to remind these jurors that he's a

1 practicing physician. So what I would insert is just to  
2 simply say "practicing physician in the Charleston area,"  
3 and substitute that for either of the other versions you all  
4 propose.

5 Dr. Brueckmann. The defendant complains that this last  
6 statement by her where she -- where in the summary plaintiff  
7 says Boehringer's duty to minimize risk to patient, the  
8 defendant says is an incomplete characterization. And I  
9 wondered what you meant by that was incomplete or what --

10 MR. HAILEY: Well, so, our objection, Your Honor,  
11 was that this is highlighting one piece of Dr. Brueckmann's  
12 testimony also in a way that suggests that, or focuses on  
13 the fact that she, she made this one statement about a  
14 potential duty while sort of not emphasizing the, her  
15 testimony in a more holistic manner.

16 THE COURT: What would you, what would you say  
17 should be added to make it more holistic?

18 MR. HAILEY: Well, I think for this we'd be fine  
19 in stating this in a more neutral manner to say whether or  
20 not Boehringer has a duty to minimize risk to patients.

21 MR. LEWIS: Or we could even -- not to interrupt,  
22 Your Honor, but I was just thinking or just generally  
23 Boehringer's duties to patients in a generic way rather than  
24 focusing on minimizing the risk.

25 MR. CHILDERS: That was the only duty that she

1 talked about, Your Honor. We kept it really short with her.

2 THE COURT: That's pretty close to just a direct  
3 quote from her deposition. So I disagree. I'm going to  
4 leave that in.

5 Next, and I think this is actually in two places.  
6 First, on slide 9 and then again on slide 10 where in  
7 plaintiffs' summary they want to describe it as the family's  
8 decision to switch Betty Knight from warfarin.

9 Defendant objects to that. And I think I agree with  
10 the defendant. It was not just a family decision because  
11 Dr. MacFarland and her office participated in it. So just  
12 take out "family." Just refer to the decision to switch  
13 her.

14 MR. CHILDERS: Might I offer --

15 THE COURT: Sure.

16 MR. CHILDERS: And I thought about this over the  
17 weekend too.

18 THE COURT: Okay.

19 MR. CHILDERS: If we put the word "family's  
20 decision to request Betty Knight's switch," I think that was  
21 accurate from all the testimony we heard.

22 THE COURT: I don't disagree with that.

23 MR. HAILEY: I think, I think we'd be inclined to  
24 go with Your Honor's first proposal which is just, I think,  
25 a simpler statement and, and reminds the jury of the topic

1 of her, of Mr. Knight and Ms. Stevens' testimony rather than  
2 really suggesting --

3 THE COURT: Yeah, I'm going to agree with the  
4 defendant.

5 MR. CHILDERS: Okay.

6 THE COURT: His testimony was not just their  
7 family meeting but they were at the meeting with the nurse.  
8 So just take out the word "family" there.

9 MR. CHILDERS: Okay. Just the decision? Yes,  
10 sir.

11 THE COURT: Yes, and then in Claudia's similar  
12 statement.

13 MR. CHILDERS: Okay.

14 THE COURT: And then next the defendant objects  
15 again to both of the childrens' slides about including the  
16 statement "Betty Knight's prior history reading medication  
17 labels." And that's what they testified about.

18 Certainly it's a dispute in the evidence and you can  
19 argue that the jury could reject the inference that  
20 plaintiffs are claiming from their literal testimony. But  
21 just to say that they testified about Betty Knight's prior  
22 history of reading medication labels, to me that's neutral.

23 MR. HAILEY: Well, I, I think BI's objected to  
24 this on really two grounds. One, we think it's inconsistent  
25 with the testimony for the reasons we argued at the directed



1 verdict stage.

2 The testimony was that Mrs. Knight may have read a  
3 label for a statin drug specifically. But, but this  
4 statement here suggests that she had some broader history or  
5 practice of reading medication labels.

6 And since this is a disputed issue, I think it's just  
7 inappropriate to be framing it in this way in what's  
8 supposed to be sort of a more neutral presentation to the  
9 jury.

10 THE COURT: What would you suggest as an  
11 alternative to refresh their recollection because they did  
12 testify -- it's a little differently -- about facts from  
13 which a jury may infer that Betty read labels.

14 MR. HAILEY: Well, if, if the issue here is  
15 whether or not Mrs. Knight read labels, and that's what the  
16 testimony is going to, I think we'd suggest that the bullet  
17 read whether or not Mrs. Knight read medication labels. And  
18 that doesn't suggest one way or the other. It's more of a  
19 neutral statement.

20 MR. CHILDERS: I think they're both neutral. I  
21 think what we said was neutral as well.

22 THE COURT: I'm going to leave it as it is. I do  
23 intend to make clear to the jury before and after this is  
24 given that this is not evidence and it's merely a summary to  
25 help remind them of what the evidence was about and what the

1 testimony was about.

2 You guys are going to argue this like crazy if it gets  
3 to that anyway. So I don't think it's necessary to give a  
4 more detailed sort of summary of the evidence. So I'm going  
5 to leave it as it is.

6 And then the last one, the reference to Dr. Huh's  
7 testimony, it was very short testimony. First you object to  
8 them making reference to epinephrine not stopping the  
9 bleeding.

10 MR. HAILEY: Yeah. So that's, that's just  
11 inconsistent with the testimony. The question was did  
12 the -- the question from plaintiffs' counsel was the  
13 epinephrine didn't stop the bleeding. And the response was  
14 it slowed the bleeding. That's what it's designed to do.  
15 So I think that's -- it's sort of a misleading statement of  
16 the testimony. And --

17 THE COURT: Okay. I, I think I agree with that.  
18 Why don't you change it to say epinephrine slowed but did  
19 not stop the bleeding.

20 MR. HAILEY: And -- well, I think just more  
21 broadly highlighting these details about the procedure, I  
22 mean, I think if we wanted to give a more balanced view of  
23 the testimony, the take away from the testimony is that this  
24 was a standard procedure.

25 THE COURT: Talking about Dr. Huh's testimony.

1 MR. HAILEY: Yes. It was a standard procedure and  
2 didn't require any incisions. Mrs. Knight was in stable  
3 condition after the procedure. Dr. Huh had no expectation  
4 that there would be further bleeding.

5 So I think our broader concern is just that by  
6 highlighting this, these isolated details, it's, it's trying  
7 to tip the scales one way or the other. And we'd suggest  
8 just leaving it as testified about the procedure he  
9 performed and leaving it at that without adding all this  
10 additional detail.

11 MR. CHILDERS: That's fine, Judge. We were just  
12 trying to include facts. But if that's a problem --

13 THE COURT: Well, are you willing to just accept  
14 their --

15 MR. CHILDERS: Yeah. I don't want to make the  
16 shortest deposition play have the most amount of information  
17 under it on the slide --

18 THE COURT: Okay.

19 MR. CHILDERS: -- like it sounds like we're going  
20 to have to do otherwise.

21 THE COURT: Okay. So you'll just leave it at --  
22 just eliminate those last three bullet points.

23 MR. CHILDERS: Sure.

24 MR. MOSKOW: How about testified about the  
25 procedure he performed to stop the bleeding.

1 THE COURT: I don't mind that. I mean, I think  
2 it's probably good to remind them which procedure this was.

3 MS. JONES: I think that's fine, Your Honor.

4 THE COURT: Okay. So put that in. Okay.

5 MR. MOSKOW: I'm going to run this out to our tech  
6 person.

7 THE COURT: Yeah. I was just going to ask what  
8 you need to do.

9 MR. LEWIS: So, Your Honor, how will this be  
10 presented?

11 THE COURT: Well, the way I would suggest is I  
12 would introduce this by saying that at my direction, I asked  
13 the parties to confer and prepare a brief summary so as to  
14 refresh the recollection of the jury about the evidence that  
15 they heard last week since we've had this now four-day  
16 interruption, and that this is merely a summary and not in  
17 and of itself evidence and they won't see this again. It's  
18 not an exhibit that's going to be introduced, and that they  
19 should bear in mind that they decide what the evidence is  
20 and what the facts are.

21 And then I will let them -- I've got to let them show  
22 it and then remind them at the conclusion of it again this  
23 wasn't evidence. This was just a summary because we've had  
24 this four-day interruption.

25 MR. LEWIS: Should we liken it to an opening

1 statement or a closing argument so they have some conception  
2 that this is the lawyers talking and not the evidence?

3 THE COURT: Well, I'm going to make it clear this  
4 was prepared by the lawyers. And I think that's so  
5 self-evident I don't think it needs to be said. And I don't  
6 want to compare it to an opening statement because then it  
7 sounds like it's coming from just one side or something.  
8 It's a summary --

9 MR. LEWIS: Okay.

10 THE COURT: -- now essentially prepared by the  
11 lawyers with even a few minor disagreements remaining. I  
12 understand that you still disagree with some of my rulings  
13 on this, but I think it's just that.

14 And I intend to just say it that way for them, that  
15 this is just because we've had this interruption and as a  
16 result -- I don't even want to call it an interruption. I  
17 don't want to make it sound negative, you all interrupted.  
18 This delay and that's the purpose of it.

19 MR. LEWIS: And do you want us to -- so I assume  
20 that the lawyers for the plaintiff will read theirs. Do you  
21 want us to read Dr. Huh? I mean, technically he was in our  
22 case.

23 MR. CHILDERS: That's fine.

24 THE COURT: Are you going to read this or just  
25 show it to them?

1 MR. CHILDERS: Our expectation was to read it just  
2 to make sure that there was enough time up on the screen so  
3 they could see it. I don't know how else to really time it.

4 THE COURT: Okay. We'll do it that way.

5 MR. LEWIS: Okay. Thank you.

6 MR. CHILDERS: And I'll just word-for-word read it  
7 obviously.

8 THE COURT: Right, okay. So then let's go to the  
9 motion regarding Dr. Crossley. I've read all of it,  
10 including the attachments.

11 First, the defendant -- or plaintiff raised the  
12 objection that Dr. Crossley might be testifying about aPTT  
13 and INR levels for Betty Knight while she was on warfarin.

14 My understanding is from looking at the reports, first  
15 he does discuss this probably more thoroughly in terms of  
16 the principles involved in his general report.

17 I found that in his case specific report he made one  
18 reference to the fact that Betty warfarin (verbatim) had  
19 aPTTs -- and I don't know if he included INRs in this or  
20 not -- but aPTT levels that were above normal while she was  
21 on warfarin.

22 And then clearly he was asked about this when he was  
23 deposed specifically. And, as I recall, he talked about two  
24 or three specific aPTT or INRs while Betty was on warfarin.

25 So I think it's there. I think it's out there and I

1 think that's adequate notice.

2 MR. ABNEY: Can I --

3 THE COURT: Yeah.

4 MR. ABNEY: -- jump in and give you a different  
5 perspective?

6 THE COURT: Sure.

7 MR. ABNEY: So in his general report he talks  
8 about, like all doctors do, warfarin patients have to have  
9 their blood checked and the INRs, you know, you have to  
10 adjust the medication. Nobody likes that.

11 THE COURT: Right.

12 MR. ABNEY: His case specific report for Ms.  
13 Knight, he doesn't mention INR any place, any time,  
14 anywhere.

15 THE COURT: One reference to aPTT.

16 MR. ABNEY: And here's the difference. This is  
17 like saying we have, you know, a test to look at red blood  
18 cells and a test to look at white blood cells. He's talking  
19 about one in his expert report.

20 And in his deposition Mr. Childers asked him about that  
21 one statement he has about aPTTs. And now he wants to come  
22 into court and talk about a totally different test that he  
23 has never referenced anywhere. And they're completely  
24 different studies. They're different tests.

25 The INR, which is based on the PT test, is used to

1     adjust warfarin doses. The PTT or aPTT is a different test  
2     that looks at different clotting factors in the clotting  
3     cascade. And it's FDA approved by a couple of manufacturers  
4     to look at Heparin patients. The label says you can use it  
5     to look at Pradaxa patients. But nobody is talking about  
6     aPTT being a surrogate or something similar to an INR for  
7     warfarin patients.

8             So in his report he only references aPTT because he  
9     read Dr. Ashhab's report. And he says Dr. Ashhab was  
10    looking at her aPTT results and said that indicates she's  
11    over-anticoagulated on Pradaxa because the Pradaxa label  
12    says you can look to aPTT to see how anticoagulated a  
13    patient is from Pradaxa. So that was Dr. Ashhab's statement  
14    and what he testified to.

15            So Dr. Crossley says, well, that's not a valid  
16    statement because her aPTT was elevated before she ever went  
17    on Pradaxa, suggesting that maybe she just had an abnormal  
18    aPTT whether she's on Pradaxa or not.

19            So that was a statement in his expert report was  
20    Dr. Ashhab's wrong because her aPTT was elevated before she  
21    ever went on Pradaxa. So looking at aPTT for Pradaxa is a  
22    fallacy. That was what his report said.

23            Mr. Childers then said, "Okay, was she  
24    over-anticoagulated before she went on Pradaxa when her aPTT  
25    was elevated?" And Dr. Crossley said, "No, she wasn't."



1           So then Mr. Childers pulls out each one of those lab  
2 tests where she had her aPTT and it was elevated. And she  
3 also had an INR which was elevated. And she was on  
4 warfarin.

5           So Dr. Crossley says, "Well, yeah, you're right. She  
6 was over-anticoagulated. She was on warfarin." They looked  
7 at her INR. It was elevated. Warfarin can also elevate  
8 aPTT. So that's why her aPTT was elevated. That was the  
9 entire testimony.

10           He has never in any semblance said, "I think she was  
11 out of therapeutic range a lot. I don't think she was an  
12 appropriate candidate for warfarin. I have opinions that  
13 are based on her INRs."

14           He's never said any of that. In fact, in his  
15 deposition he said, "I think it would have been appropriate  
16 for them to keep her on warfarin."

17           And now he wants to show up and put up 50 different INR  
18 readings and talk about how she was out of range and she  
19 wasn't well controlled on warfarin and her risks were  
20 astronomical. None of that he ever disclosed in his report  
21 or in his deposition. This is just total trial by ambush,  
22 Judge.

23           MS. PEREZ: I mean, I'm just looking at the  
24 deposition here Page 238, line 18. "If you're on warfarin  
25 and your INR is over 3, aren't you considered to be

1 over-anticoagulated?"

2 And then later, "If you have an INR of 3.7 is that  
3 considered to be over-anticoagulated?"

4 "Yes."

5 "If you have an INR of 4.3 is that considered to be  
6 over-anticoagulated on warfarin?"

7 "Correct."

8 The plaintiffs' counsel then goes on to pull out Ms.  
9 Knight's specific records where she has those INRs and show  
10 them Dr. Crossley.

11 I mean, the plaintiffs could have explored this further  
12 in the deposition. The fact that they chose not to is not a  
13 reason to preclude Dr. Crossley from testifying to these  
14 facts.

15 I mean, the fact is he spoke about INR variability in  
16 some detail, as you mentioned, in his general report. He  
17 spoke about how she had a bleed on warfarin in his specific  
18 report and how the switch to Pradaxa was appropriate.

19 The idea that the plaintiffs are somehow surprised by  
20 this opinion when this has been a central theme in the case  
21 I just think is not credible.

22 MR. ABNEY: Well, first of all, Judge, it wasn't a  
23 central theme in this case until they raised it on  
24 cross-examination of our expert. None of their experts have  
25 put together this chart that they're talking about showing

1 and using and arguing that she was out of INR range.

2 The, the INRs that were talked about in that deposition  
3 were only because Dr. Crossley incorrectly said she had aPTT  
4 elevation before Pradaxa. And that's, you know, that was  
5 the whole issue.

6 THE COURT: Well, I'm sorry. Go ahead.

7 MR. ABNEY: He, he never, ever said, "My opinions  
8 are based on her INR readings," or, "I think she was out of  
9 range." He said it was inappropriate for them to keep her  
10 on warfarin.

11 They want to come in and talk about 50 readings because  
12 he was cross-examined on four. And, you know, we could have  
13 followed up. He never gave us any indication that there was  
14 anything to follow up on.

15 He never said she was out of therapeutic range on  
16 warfarin. He never said, "I don't think warfarin was good  
17 for her because she was out of range a lot." He never said,  
18 "I have opinions that are based on her INR readings." He  
19 never mentioned her INR readings one time ever. And now he  
20 wants to come in and testify that's a central focus of his  
21 testimony.

22 THE COURT: Well, I disagree. I agree with the  
23 defendant. The issue of INRs and what the therapeutic range  
24 is, whether it's evidence of, of over-anticoagulation or not  
25 was raised and he was asked several questions about it.

1           So I don't think I can restrict him to just the one or  
2 two that you all asked him about. He clearly offered  
3 opinions about how to characterize those particular INRs.  
4 That at a minimum put you on notice that he's got opinions  
5 about the significance of those INR readings.

6           And if he said the things that you just said, some of  
7 which I see that he did, some of which I don't know,  
8 cross-examine him with it. And if he admitted that, that he  
9 never -- you have said that he never claimed that she was  
10 over-anticoagulated on warfarin.

11           So you can cross-examine him if he now tries to say,  
12 "Oh, yeah, this was -- warfarin wasn't working for her the  
13 whole time." I think that's, I think that's something  
14 you're just going to have to pursue on cross-examination.

15           As to the second, as I understand it, defendant agrees.  
16 And the issue there was the extent to which Crossley might  
17 testify about what the FDA considered and whether they  
18 approved or didn't approve of certain things.

19           The defendant acknowledges that this Court issued a  
20 ruling pursuant to plaintiffs' motion to limit that  
21 evidence. And they've indicated that they intend to abide  
22 by it.

23           I went back and re-read those four or five pages of the  
24 opinion and I think that it was pretty clearly stated. And,  
25 so, I expect them to live with that.

1 MS. PEREZ: Yes, Your Honor.

2 And we just want to clarify as to the topics that we  
3 listed in our opposition to the motion, the fact that, you  
4 know, he is a practicing cardiologist. He prescribes  
5 Pradaxa in accordance with the FDA approved label which does  
6 not require monitoring and the effect he sees on his  
7 patients from that. We think that is not precluded by the  
8 Court's order and we just wanted to confirm.

9 THE COURT: I agree. I don't think that would be  
10 precluded by it.

11 MR. ABNEY: And we're not arguing that, Your  
12 Honor.

13 THE COURT: Right.

14 MR. ABNEY: We gave you some examples. I mean,  
15 he, he would make a statement and when he was asked, "What  
16 data do you have to support that statement," he would run  
17 back to his, you know, talking point of, "Well, the FDA  
18 reviewed all of that data and they approved it as safe and  
19 effective, so that's the data I'm talking about."

20 THE COURT: Uh-huh.

21 MR. ABNEY: And I think that's improper.

22 MS. JONES: Just to be clear, I do think on the  
23 condition he is permitted to say, "When I make judgments  
24 about whether a medicine is appropriate, part of what I rely  
25 on is the FDA's judgment based on his review of the data."

1 I don't think that's an inappropriate statement for him to  
2 offer as a clinician.

3 THE COURT: I agree, but I think he probably needs  
4 to stop there because I think when he starts trying to get  
5 into an answer that implicates the data and the analysis  
6 underlying it, he's going beyond what he can do.

7 MS. JONES: Okay, understood.

8 THE COURT: Okay? All right. We're on track for  
9 your witnesses this morning?

10 MS. JONES: They are here.

11 MR. LEWIS: Yes. We'll start with Dr. Shami.

12 THE COURT: Okay. I've, I've gone through most of  
13 the instruction issues that you left me with last week. I'm  
14 going to be working through the day with Blake to try to put  
15 those into some draft shape.

16 My plan at this point would be to try to get that to  
17 you most likely right after lunch, give you the afternoon  
18 and a while this evening. I'm probably -- depending on how  
19 long we go with these witnesses, I'm probably going to  
20 require you to stay over this evening after we finish the  
21 evidence today, whatever we get through, to take up the  
22 instructions and try to wade through most of it, if not all  
23 of it.

24 Do you still sense that we're probably looking at a day  
25 and a half of testimony for these two experts?

1 MR. LEWIS: Yes.

2 THE COURT: Okay. So we'll kind of track that.

3 But I, I want to keep moving towards final instructions and  
4 certainly still intend to make sure that we have an adequate  
5 conference on the record to let each side voice any final  
6 objections.

7 And then did you get anywhere with the verdict form  
8 yet?

9 MR. CHILDERS: We sent out a version yesterday  
10 afternoon. Hopefully we'll hear back from the defendants.

11 MS. JONES: I don't think our views on what we  
12 talked about last week have changed. I think the only  
13 change we got yesterday was something in a particular part  
14 of the verdict form. So we'll need some time with the Court  
15 on that because we do have probably four or five material  
16 issues we need to sort through.

17 THE COURT: Okay.

18 MS. JONES: And I assume both sides will want to  
19 use the verdict form in closing. So with that in mind --

20 THE COURT: Sure. Well, I haven't looked at what  
21 was originally submitted by either side yet. Is your  
22 proposal yesterday significantly different from that? Do  
23 you remember?

24 Why don't you all just send Blake your latest version,  
25 understanding that you all haven't read it yet, or at least

1 haven't finished reviewing it yet. And then maybe you can  
2 let us know later this morning or at noon when you expect to  
3 have a counter proposal or something so we can at least  
4 start seeing where the differences are between the two  
5 approaches.

6 MS. JONES: Okay.

7 THE COURT: Is there anything else we need to take  
8 up before we start?

9 MR. CHILDERS: We did have a few outstanding  
10 objections to the exhibits they told us they were going to  
11 use. We can start with Dr. Shami I guess.

12 THE COURT: All right.

13 MR. CHILDERS: I'm sorry. I'm having to do this  
14 off the top of my head.

15 MR. LEWIS: There were four objections.

16 MR. CHILDERS: The first was the Coumadin label  
17 which she did not list as a reliance material in either of  
18 her reports and did not reference specifically in her  
19 report. Also the Plavix label, same issue. She didn't, she  
20 didn't list it as a relied upon material or reference it  
21 specifically in her report.

22 The death certificate, believe it or not, was not  
23 something that she relied on either or listed as a reliance  
24 material in any of her reports.

25 And then, finally, that summary INR chart that we have



1 sort of been talking about today with Dr. Crossley, we had  
2 objections to some of the slides being incorrect. We gave  
3 those to the defendants on Wednesday. They did send us back  
4 a new version but it was after 10:30 last night and we  
5 haven't had a chance to go through it. It's a very  
6 voluminous document.

7 And, so, we object to using that with either of these  
8 witnesses until we actually have some time to go through  
9 page by page to make sure that it was changed.

10 THE COURT: Okay. So you wouldn't object to them  
11 using the underlying INR report but not using the chart.

12 MR. CHILDERS: Correct.

13 THE COURT: Well, I think under the circumstances  
14 my understanding was at the time you presented it, you  
15 agreed that you had not developed that chart in advance or  
16 given it to plaintiffs in advance. You represented that all  
17 the records underlying it were attached.

18 I have no problem with you using the underlying  
19 records. But if there's a dispute that remains about the  
20 accuracy of the chart, then you probably best use the  
21 underlying records so we don't have a problem.

22 MR. LEWIS: Well, I intend to use what I've used  
23 before which was the demonstrative that shows the in and out  
24 of range for the INR that was created. That's not going to  
25 go back to the jury.

1 THE COURT: Right.

2 MR. LEWIS: And then we have the -- let the  
3 plaintiffs have more time to review the summary I guess. I  
4 mean, we made the corrections that they asked us to make. I  
5 don't know why that's going to be such a hold-up, but I  
6 would ask that they promptly look at that.

7 THE COURT: When is the, that person expected to  
8 testify?

9 MR. LEWIS: Dr. Shami is going to be the first  
10 witness.

11 THE COURT: First?

12 MR. LEWIS: Again, I can work through the  
13 examination by only using the demonstrative, but I  
14 definitely want to get that document into evidence. And  
15 we've done what the plaintiffs have asked us to do on that  
16 document.

17 THE COURT: Well, how much more do you think --  
18 how much more time do you think you need to review it?

19 MR. CHILDERS: When we got it the first time it  
20 took a few hours to go through because it was -- you saw --  
21 a lot of pages. And we found mistakes. So we want to make  
22 sure, again, that mistakes were corrected.

23 MR. LEWIS: Well, if I recall correctly, the  
24 request was to add additional INR readings that were in the  
25 medical records to the chart, which is what we did.

1 MR. CHILDERS: That's not accurate, Judge. That's  
2 not -- we had a whole list of requests, I'm happy to share  
3 them with the Court, that related to incorrect information  
4 being on the chart, having INRs listed when she was on  
5 Pradaxa, not warfarin, having the same reading listed more  
6 than once. I mean, there were all kinds of issues.

7 THE COURT: Well, given that plaintiffs have  
8 raised that objection, and I'm going to take Mr. Childers at  
9 his word that they go beyond just additions, you can't  
10 authenticate the chart at this point.

11 MR. LEWIS: Okay.

12 THE COURT: So I couldn't let you use it unless we  
13 get to that point.

14 MR. LEWIS: Understood.

15 MS. JONES: But Your Honor's question I think is  
16 well-taken because we're raising it toward the end of trial.  
17 We're going to be very soon at the end of our case where we  
18 would want all of the evidence we need in the record.

19 I understand we just sent it to you last night, but  
20 what is a realistic time frame for getting that I think is  
21 the question that we would have at this juncture.

22 THE COURT: Well, I don't want to invite them to  
23 go into a stall tactic here. The problem is this, this is a  
24 piece of evidence --

25 MS. JONES: Uh-huh.

1 THE COURT: -- that you all probably should have  
2 presented to them before trial and said, "Here's the chart  
3 that we want admitted into evidence under the rule that is a  
4 substitute for all of the underlying documents that are  
5 voluminous."

6 So it's your-all's burden to establish those things and  
7 I'm not faulting either side. But if you wait until trial,  
8 you run the risk that they don't have time or not only do  
9 they have a shortage of time to go through it, they find  
10 things wrong that throw it into doubt. So that seems to be  
11 where we are.

12 MS. JONES: But using a collection of the  
13 underlying records is not an issue with the witnesses today.

14 THE COURT: Well, if they're authenticated  
15 otherwise, no. And I don't think there's been any dispute  
16 from either side that --

17 MS. JONES: Okay.

18 THE COURT: -- about medical records. But if the  
19 chart becomes the evidence, you have to authenticate it to  
20 get it into evidence. And right now I don't think that's  
21 going to be successful given the level of problems Mr.  
22 Childers has got.

23 MR. LEWIS: Okay.

24 THE COURT: So, then, these other three, so what  
25 do you say?

1 MR. LEWIS: So on the death certificate, the death  
2 certificate was right in the medical records that were  
3 collected from Salim-Beasley. There's a --

4 MS. JONES: We disclosed it.

5 MR. LEWIS: They reviewed all the medical records.

6 THE COURT: The way I view this is really this is  
7 the way they've raised it. I'm assuming there's kind of two  
8 issues. But one is getting the document in. That death  
9 certificate is already here in evidence.

10 MR. LEWIS: It's already in.

11 THE COURT: So really what they're saying is she  
12 didn't rely upon it in her disclosures, so she can't now  
13 rely upon it to give an opinion. So how were you intending  
14 to use it?

15 MR. LEWIS: Well, she indicated that she reviewed  
16 all of the medical records that were provided by the  
17 plaintiffs. And there's a Bates number right on the death  
18 certificate that indicates that it's from Salim-Beasley LLC  
19 which is the entity that was used to produce the medical  
20 records.

21 THE COURT: I haven't seen the report. So what  
22 did she conclude about it?

23 MR. LEWIS: She says that the death summary  
24 indicated that cardiac arrest was the cause of death. And  
25 that's in her case specific report. It's the very last

1 sentence of her report.

2 MR. CHILDERS: I agree she said that. The death  
3 summary is a medical record. It's not the death  
4 certificate. The records that she reviewed, she  
5 specifically listed out from each provider. She didn't say,  
6 "I looked at every medical record that plaintiffs produced."

7 And what she listed as -- what she says was listed in  
8 the death summary as the cause of death is not what it says  
9 on the death certificate. So I don't believe they have  
10 referenced it. They definitely didn't -- she definitely did  
11 not list it as a specific document that she relied on for  
12 her report.

13 MR. LEWIS: It wasn't -- I'm sorry. I didn't mean  
14 to interrupt you.

15 MR. CHILDERS: I'm trying to find the report, Your  
16 Honor, so we can see specifically what we're talking about  
17 and not have to think of it in a vacuum.

18 MR. LEWIS: It's not, it's not individually as one  
19 page called out as reliance material in her report, but she  
20 relied on the medical, voluminous medical records which were  
21 provided by the plaintiffs in this case. They produced a  
22 Bates numbered set of medical records. The death  
23 certificate is -- I believe it's Bates Number 1 if I recall  
24 correctly of the records that were provided by the, by the  
25 plaintiffs. So she's familiar with the document.

1 MR. CHILDERS: This is her report.

2 MR. LEWIS: She testified and gave an opinion in  
3 the very last summary of opinions that the recognized cause  
4 of death.

5 THE COURT: Well, what, what do you think she's  
6 referring to when she says --

7 MR. CHILDERS: There's a medical record actually  
8 called a death summary that more closely follows this. The  
9 death certificate doesn't say cardiac arrest anywhere. It  
10 says cardiopulmonary arrest. And then it says myocardial  
11 infarction.

12 She's talking about a medical record. She's not  
13 talking about the death certificate. I don't have any  
14 problem with her talking about of any these records that she  
15 listed. But I went and looked through all these records and  
16 the death certificate wasn't included in any of them. It's  
17 a separate document.

18 MR. LEWIS: She has indicated --

19 THE COURT: Well, do you intend -- so what are you  
20 objecting to exactly then? I thought you were objecting to  
21 the exhibit.

22 MR. CHILDERS: I'm objecting to her relying on an  
23 exhibit that she's never told us she's ever utilized.

24 MR. LEWIS: She's clearly offered -- I mean, she  
25 referred to -- there are various documents that talk about

1 the cause of death. She's seen the death certificate. It's  
2 not inconsistent.

3 THE COURT: Honestly, I think they can ask her  
4 what she relied upon. And if she says she's seen the death  
5 certificate, she can testify about the death certificate.  
6 If she -- you can cross-examine her about what -- if that's  
7 actually what she had seen, that she didn't use the same  
8 phrase.

9 I can't tell from that what she relied upon, but I  
10 don't think it's sufficient for me to exclude that she might  
11 have been relying upon the death certificate that's part of  
12 the medical records.

13 MR. LEWIS: On the label -- the labels for Plavix  
14 and Coumadin were not specifically listed as reliance  
15 materials. The basis for her looking at those are that  
16 she's been a practicing physician, gastroenterologist, seen  
17 those labels numerous times throughout her practicing career  
18 and that's -- and her opinions are premised upon her  
19 training and experience and in treating other physicians in  
20 addition to reviewing the medical records.

21 THE COURT: Well, but an expert has to disclose  
22 the basis of their opinions when you're using them as an  
23 expert witness, not just a treating physician. And if she  
24 provides an explanation in her reports of what she relies  
25 upon, then, yes, she may well have seen the Coumadin label



1 500 times. But if she doesn't say, "I'm relying upon the  
2 Coumadin label," she can't rely upon it now.

3 MR. LEWIS: Well, may I?

4 THE COURT: Yes.

5 MR. LEWIS: When it's something broadly, training,  
6 experience, and treating patients as a basis, and that  
7 encompasses reviewing labels, then that's fair game for her  
8 to rely upon her review of those labels for purposes of her  
9 opinion.

10 To the extent that there were specific records that  
11 otherwise wouldn't be encompassed within her training and  
12 experience as a clinician, a practicing clinician, those  
13 were specific recall. Her general report talks about  
14 warfarin and all of the various risks associated with it  
15 that she's familiar with from her practice. So the label is  
16 a supplement to that, that testimony.

17 THE COURT: Well, that strikes me that the label  
18 is becoming additional evidence beyond what she testified  
19 about or explained as the basis for her opinion.

20 MR. LEWIS: I can just ask her if she's reviewed  
21 the label and is familiar with risks of these particular  
22 medicines as part of her training and experience and not  
23 introduce the label itself.

24 THE COURT: I think you can do that.

25 MR. LEWIS: Okay.

1 MR. CHILDERS: Understood. Same with the Plavix  
2 label I take it, Your Honor.

3 MR. LEWIS: Yeah. I was covering both of them.

4 THE COURT: Okay, all right.

5 MR. LEWIS: And then there was one other issue I  
6 believe.

7 THE COURT: There was four. That's four.

8 MR. LEWIS: Was that four? Okay.

9 MS. JONES: There were issues as to Dr. Crossley.  
10 Some of them are overlapping. We've talked about the INR  
11 issue. I assume that Your Honor's ruling would apply  
12 equally -- I'm sorry, I'm losing my voice a little bit --  
13 would apply equally as to the death certificate for Dr.  
14 Crossley, but we can certainly talk about that in greater  
15 detail if that's not the case.

16 THE COURT: I don't know what you mean.

17 MS. JONES: Well, they've raised a similar  
18 objection to Dr. Crossley being shown the death certificate  
19 for Mrs. Knight during his direct examination whenever we  
20 get to that.

21 I think our response would be fundamentally the same,  
22 which is these people, at least experts, have plainly  
23 disclosed opinions on the cause of death. And he, I think,  
24 specifically invoked myocardial infarction and referenced  
25 the fact that he had looked at the medical records. So I

1 think the analysis would be the same.

2 THE COURT: Okay. I see what you're saying. I  
3 agree.

4 MS. JONES: There's a reference to additional  
5 medical records and I'm not even sure exactly what this one  
6 is. Okay. The 9017 is not an issue. And then there was an  
7 article that they've objected to. Let us confer about that.  
8 We may be able to work that out.

9 THE COURT: Okay. I haven't seen any of this.

10 MR. MOSKOW: Our agreement is that we object by  
11 8:00 a.m. in the morning. We disclose by 8:00 p.m. the  
12 previous evening and we object and try to work through them.

13 MS. JONES: May I raise one other issue?

14 THE COURT: Yes.

15 MS. JONES: You had asked us to go back and take a  
16 crack at revising the failure to test jury instructions. We  
17 had them emailed over the weekend. We couldn't reach  
18 agreement. Should we just go ahead and submit our  
19 respective proposals on that so you can consider that?

20 THE COURT: Yes.

21 MS. JONES: Okay.

22 THE COURT: Did you intend to offer some  
23 instructions concerning the Medication Guide?

24 MS. JONES: Well, I guess we were intending to be  
25 guided by however Your Honor ruled on the directed verdict

1 motion.

2 THE COURT: Well, at this point, I think -- I'm  
3 still reserving judgment on it. I am considering that I may  
4 agree with you in part such that I would instruct the jury  
5 in a limiting instruction concerning the theory that the  
6 Medication Guide issue has been relied upon by plaintiffs as  
7 part of the failure to warn. I don't want to go through  
8 that whole discussion again. You know what I'm talking  
9 about.

10 MS. JONES: Yeah.

11 THE COURT: So if you're going to offer an  
12 instruction about that, I'd like you to prepare that.

13 MS. JONES: Okay.

14 MR. LEWIS: May we have two or three minutes? I  
15 just want to inform the witness of the rulings.

16 THE COURT: Yes. What time is it?

17 MR. MOSKOW: It's about a quarter of, Your Honor.

18 THE COURT: Okay. Yeah.

19 MR. LEWIS: Thank you, Your Honor.

20 MS. JONES: Thank you, Your Honor.

21 MR. MOSKOW: Thank you, Your Honor.

22 (Recess taken from 9:46 a.m. until 9:50 a.m.)

23 THE COURT: Good morning. All right, so we're  
24 ready to proceed?

25 MR. CHILDERS: Yes, Your Honor.

1 MR. MOSKOW: May I have 30 seconds, Your Honor?

2 THE COURT: Yes.

3 MR. LEWIS: Your Honor, we're going to start with  
4 the summary.

5 THE COURT: Yes. That's what I was going to do  
6 first.

7 MR. MOSKOW: All set, Your Honor.

8 THE COURT: All right. Let's bring the jury out.

9 (Jury returned into the courtroom at 9:52 a.m.)

10 THE COURT: Good morning, ladies and gentlemen.  
11 Be seated.

12 Welcome back. I think I may have mentioned when we  
13 left here on Wednesday it's unusual to have a four-day  
14 hiatus break in a trial like this. And, so, I've decided  
15 and so inform you all and the parties that I wanted the  
16 parties to prepare some type of a brief summary of the  
17 testimony of the witnesses that you've heard thus far as an  
18 aid to refresh your recollection as we start again this  
19 morning.

20 Today you're going to be hearing witnesses from the  
21 defendant. But before we do that, I'm going to ask that the  
22 parties provide this brief summary. I've reviewed it.

23 I want to stress that this is just a summary that the  
24 Court has asked the parties to develop as an aid to refresh  
25 your recollection. It is not evidence. It is not an

1 exhibit that will be introduced into evidence. It is not  
2 any attempt by the parties or the Court to state to you what  
3 the facts are that you must find. Rather, it is simply to  
4 help refresh your recollection about who testified.

5 As part of this they're going to show you the  
6 photograph of the person who testified. A couple of these  
7 were live witnesses. Some are videotape witnesses that  
8 you've seen.

9 So as the parties do this, I'm going to ask first the  
10 plaintiffs to go through their witnesses. As you recall,  
11 they completed their case. The defendant had only called  
12 one witness. And, so, they're going to present that one  
13 last. It was very short.

14 But, again, this is just to help bring back your  
15 recollection of these people and the testimony. It will  
16 always be your responsibility to decide what the evidence  
17 was and what the facts are of this case.

18 With that, Mr. Childers, you can present the  
19 plaintiffs' portion.

20 MR. CHILDERS: Thank you, Your Honor.

21 Good morning, everyone. Can everybody hear me okay?  
22 All I'm going to do is read what's on the, the slides.

23 The first witness was Dr. Jeffrey Friedman, therapeutic  
24 area head, cardiovascular, Boehringer. Testimony addressed:  
25 Pradaxa development; Pradaxa's safety risks and

1 efficacy; role of kidney -- excuse me -- role kidney  
2 function plays in Pradaxa blood levels; exclusion of  
3 patients with severe renal impairment from Pradaxa clinical  
4 trials; and identifying people at high bleed risk on  
5 Pradaxa.

6 Michelle Kliever was the second witness, Director of  
7 Regulatory Affairs for Boehringer.

8 Her testimony addressed:

9 Pradaxa regulatory issues; communications between  
10 Boehringer and the FDA regarding Pradaxa; Pradaxa's  
11 physician and patient warnings, and communications between  
12 Boehringer and the FDA regarding these warnings; and  
13 Boehringer's duty to ensure Pradaxa warnings are complete  
14 and accurate.

15 The third witness was Dr. Laura Plunkett, plaintiffs'  
16 expert witness, pharmacology, toxicology, regulatory.

17 She provided opinions regarding:

18 FDA regulatory requirements; Pradaxa's warnings and  
19 whether they are adequate; Pradaxa's safety and risks and  
20 efficacy, including the 75-milligram dose; and Boehringer's  
21 legal duty to ensure Pradaxa warnings are complete and  
22 accurate.

23 The next witness was Dr. Dawn MacFarland, Betty  
24 Knight's primary care physician when Betty Knight was first  
25 prescribed Pradaxa in October, 2011.

1           Testimony addressed Betty -- the testimony addressed  
2 Betty Knight's medical history, including her use of  
3 warfarin from the mid 2000s to October, 2011; her switch  
4 from warfarin to Pradaxa in October of 2011; and her  
5 knowledge about Pradaxa at the time it was first prescribed  
6 to Betty Knight.

7           The next witness was Dr. Ahmed Abdelgaber, Betty  
8 Knight's primary care physician from April, 2013, until her  
9 death in September, 2013. His testimony addressed Betty  
10 Knight's medical history, including:

11           May, 2013, GI bleed and hospitalization; her health  
12 issues following the May, 2013, bleed; the causes of her  
13 death. And he testified about his knowledge of Pradaxa.

14           The next witness was Dr. Joanne Van Ryn, Pradaxa's  
15 scientific support at Boehringer Ingelheim. Her testimony  
16 addressed:

17           Pradaxa's development; Pradaxa's safety and risks and  
18 efficacy; relationship between patient characteristics,  
19 Pradaxa exposure, and bleeding risk; and the increase in  
20 Pradaxa blood level increases bleeding risk.

21           The next witness was Dr. Hazem Ashhab, plaintiffs'  
22 expert witness, Board Certified in gastroenterology and  
23 internal medicine, the practicing physician in the  
24 Charleston area, provided opinions regarding:

25           Betty Knight's warfarin and Pradaxa use; Pradaxa's



1 warnings and whether they were adequate; Betty Knight's  
2 medical history, causes of Betty Knight's May, 2013, GI  
3 bleed; Betty Knight's health following the May, 2013, bleed;  
4 and causes of Betty Knight's death.

5 Plaintiffs' next witness was Dr. Martina Brueckmann,  
6 Deputy Therapeutic Area Head, cardiovascular at Boehringer.  
7 Her testimony addressed Pradaxa's development; Pradaxa's  
8 safety, risks and efficacy; the relationship between patient  
9 characteristics, Pradaxa exposure, and bleeding risk; and  
10 Boehringer's duty to minimize risk to patients.

11 Plaintiffs' next witness was Rick Knight, plaintiff,  
12 son of Betty Knight. His testimony addressed:

13 Betty Knight's family, health, work, and travel; the  
14 decision to switch Betty Knight from warfarin to Pradaxa in  
15 October, 2011; Betty Knight's prior history reading  
16 medication labels; and Betty Knight's health before and  
17 after her May, 2013, gastrointestinal bleed.

18 Plaintiffs' final witness was Claudia Stevens, also  
19 plaintiff and daughter of Betty Knight. Her testimony  
20 addressed:

21 Betty Knight's health, medications, and family life;  
22 the decision to switch Betty Knight from warfarin to Pradaxa  
23 after Claudia saw a Pradaxa television commercial; Betty  
24 Knight's prior history reading medication labels; and Betty  
25 Knight's health before and after her May, 2013,

1 gastrointestinal bleed.

2 THE COURT: All right. Mr. Lewis.

3 MR. LEWIS: May it please the Court, members of  
4 the jury, good morning.

5 Defendant's first witness was Dr. Charles Huh. He was  
6 a gastroenterologist at St. Mary's who treated Betty  
7 Knight's May, 2013, gastrointestinal bleed. He testified  
8 the procedure he performed to stop the bleeding.

9 Thank you.

10 THE COURT: All right.

11 Again, ladies and gentlemen, the summary you just heard  
12 was an aid for your use to refresh your recollections about  
13 the testimony of the witnesses. That summary was not  
14 evidence and you may not rely upon any part of that summary  
15 in determining the facts or reaching your verdict in this  
16 case.

17 With that, are we ready to call the next defense  
18 witness?

19 MR. LEWIS: Yes, we are, Your Honor.

20 THE COURT: Go ahead.

21 MR. LEWIS: Defense calls Dr. Vanessa Shami.

22 THE COURT: All right.

23 Doctor, if you'll step up here, my clerk will  
24 administer the oath.

25 **VANESSA SHAMI, DEFENDANT'S WITNESS, SWORN**

## 1 DIRECT EXAMINATION

2 BY MR. LEWIS:

3 Q. Good morning, Dr. Shami. How are you?

4 A. Good morning. I'm well. How are you?

5 Q. Could you please introduce yourself to the jury?

6 A. Sure. My name is Vanessa Shami. I'm a

7 gastroenterologist from the University of Virginia. I

8 practice -- I'm a professor there. I've been there since

9 1992.

10 So I actually started medical school there and did my  
11 formal internal medicine residency training there. I did my  
12 gastroenterology fellowship there as well, and then did an  
13 interventional, which is fellowship where I do more kind of  
14 complex procedure learning at the University of Chicago, and  
15 then came back on faculty 16 years ago.

16 Q. Okay. Thank you very much. We'll get into a little  
17 bit of your background later. But, generally speaking, do  
18 you treat patients?

19 A. I do. I treat patients four days out of the five days  
20 formally. When I'm on service or call, I'll treat patients  
21 seven days a week.

22 Q. Okay. And, generally speaking, are you also a  
23 professor?

24 A. I am. A professor basically means -- in an academic  
25 institution it means that, you know, initially you come in

1 in your clinical -- you're an assistant. Then you have to  
2 submit paperwork and prove that you've done research, that  
3 you've done accurate clinical work. Then you apply for  
4 associate; and then after that, tenure; and then  
5 professorship.

6 So it's kind of a long process, but after, after a few  
7 years, if everything is going well, then you become a  
8 professor.

9 Q. Okay. And as far as being a clinician, someone who  
10 treats patients, how long have you been doing that?

11 A. So I've been treating patients as an attending  
12 physician for 16 years.

13 Q. And how long have you been teaching med students and  
14 other students the topics that you teach?

15 A. Sixteen years as well.

16 Q. All right. And at one point in time did you treat some  
17 folks from the Charleston area?

18 A. I, I have. And, so, the thing about the University of  
19 Virginia is that we have a very large referral base. And,  
20 so, we do treat patients from Charleston a little bit more  
21 than before. I think Charleston has grown a lot and has  
22 very good physicians. But, yes, we do treat patients from  
23 Charleston.

24 Q. Okay. Now, the one thing you haven't done in 16 years  
25 is what you're doing today; right?

1 A. That is correct. This is the first time I've ever been  
2 in a courtroom.

3 Q. Okay. And, so, you don't make it a practice to testify  
4 on a regular basis for lawyers or parties in litigation; is  
5 that right?

6 A. Absolutely not. That is correct.

7 Q. All right. And this is your first time. If you're a  
8 little nervous or whatever, it's expected. We're all  
9 nervous.

10 A. I appreciate that.

11 Q. All right. Doctor, I asked you to do five things. And  
12 I want to discuss those five things with you at a high level  
13 right now and we'll get into more detail later on in the  
14 testimony.

15 But one of the, one of the five things that I asked you  
16 to do in this case was to look into whether warfarin was a  
17 safe and effective option for Mrs. Knight. Were you able to  
18 do that for me?

19 A. I was.

20 Q. And do you have an opinion about that topic?

21 A. Yes. So let me start by saying warfarin is a perfectly  
22 good drug. We've had it for many, many years. We've had it  
23 since I was in medical school. So I'm very familiar with  
24 the drug.

25 The hard part about warfarin is trying to keep it

1 within a certain range. It's very challenging for patients.  
2 It requires a certain diet. It requires blood work, dose  
3 adjustment.

4 And if you're not in that range, if it's too low, if  
5 your what we call the INR, which is the blood test that we  
6 check, if it's too low, then patients are at risk for, you  
7 know, stroke and emboli, so clots. If it's too high, then  
8 patients can have bleeding.

9 Q. Okay. And did you make a determination as to whether  
10 or not warfarin was a safe and effective option for Mrs.  
11 Knight?

12 A. I did.

13 Q. And what was that determination?

14 A. So if you look at her INRs over time, they fluctuated  
15 quite a bit. Usually we as physicians globally think of  
16 wanting to have that INR range within 2 and 3 about  
17 70 percent of the time or more.

18 Unfortunately in the case of Ms. Knight, which is very  
19 common in certain patients, that range wasn't reached over  
20 50 percent of the time. So her chances of actually having  
21 bleeding or clots form were, were high. So it was not the  
22 perfect drug for her.

23 Q. Okay. Now, the second thing I asked you to do was to  
24 look into whether Pradaxa was a safe and effective option  
25 for Mrs. Knight. Were you able to do that?

1 A. I was.

2 Q. And did you draw an opinion as to that topic?

3 MR. CHILDERS: Your Honor, I apologize. May we  
4 have a sidebar?

5 THE COURT: Yes.

6 (Bench conference on the record)

7 MR. CHILDERS: Your Honor, I have the report here  
8 for you. First, that's not one of her opinions. This is,  
9 again, not one of her opinions that's listed in her report.

10 THE COURT: Which opinion are you referring to  
11 now? About Pradaxa?

12 MR. CHILDERS: I let it go with warfarin because I  
13 thought that was the end of the questioning. She was never  
14 asked if Pradaxa is an appropriate medicine for her. In  
15 fact, she doesn't prescribe Pradaxa to patients. It's not  
16 one of her opinions. It's not included in anything she  
17 disclosed.

18 MR. LEWIS: It clearly is. Her -- all of her  
19 testimony is specific causation testimony all about Mrs.  
20 Knight. She reviewed all of the medical records and she  
21 concluded that warfarin was not a good option for her and  
22 that Pradaxa was a good option for her.

23 THE COURT: Where does she say that in the report?

24 MR. LEWIS: Can I get my note? I didn't know it  
25 was going to be challenged.

1 THE COURT: Yes.

2 (Pause)

3 MR. CHILDERS: It goes on to the next page, Your  
4 Honor.

5 MR. LEWIS: In her, in her specific report on  
6 Pages 1 and 2 she didn't --

7 THE COURT: Is this it?

8 MR. LEWIS: Yes. She goes through the extensive  
9 history of Mrs. Knight with warfarin, including the fact  
10 that she had a suspected GI bleed in 2008.

11 And in her depo she does that as well. Between Pages  
12 106 and 112 she was questioned extensively about the  
13 particular GI bleed that she had on warfarin and that was a  
14 problem.

15 Also in the specific report that Your Honor has in  
16 front of him, she indicates that the records show that she  
17 had a challenge keeping the INR in the therapeutic range  
18 which is the basis for her testimony that warfarin is not a  
19 safe option.

20 THE COURT: Where is that?

21 MR. LEWIS: It's on Page 2 of --

22 THE COURT: Okay, okay.

23 MR. LEWIS: So that was -- that's the basis of it.  
24 I mean, that's --

25 THE COURT: Well, take me to the second opinion



1 that Pradaxa was safe and effective.

2 MR. LEWIS: Right. So then she discusses in her  
3 specific report picking up in October of 2011 the fact that,  
4 number one, she had no problems with Pradaxa prior to that.  
5 And she also said she had no problems with Pradaxa prior --  
6 there were no problems indicated in the medical records with  
7 Pradaxa prior to the stent procedure and that she started  
8 triple therapy after the stent procedure in April of 2013,  
9 and that has a significant risk of bleeding with it.

10 And then she also cites to the doctor notes that talk  
11 about Mrs. Knight tolerating the Pradaxa and that it could  
12 not be held if she needed it because later on in 2013 the  
13 doctor said that she could not hold Pradaxa.

14 THE COURT: So she, she didn't offer the specific  
15 general opinion that Pradaxa was safe and effective for her?

16 MR. LEWIS: I should show you the general report  
17 as well. She did a general report and a specific report.  
18 And, so, she absolutely does in the general report. I  
19 thought the challenge was with Mrs. Knight specifically.

20 In her general report she goes through the warfarin and  
21 its risks and benefits and Pradaxa and its risks and  
22 benefits in her general report at length. Maybe I should  
23 get that for you too.

24 But when you combine the general report where she's  
25 talking generally about the safety and efficacy of the risks

1 and benefits of both drugs, and then in the specific report  
2 she applies the circumstances to this particular plaintiff.

3 MR. CHILDERS: Which would be fine, Judge, if she  
4 actually said that in her case specific report, but she  
5 never did. She didn't say that in her deposition. In fact,  
6 she said, "I don't prescribe Pradaxa."

7 And, so, to get up here and say, "I've asked you to do  
8 five things for me, one of which is tell me if Pradaxa is  
9 appropriate," that's not in the report.

10 THE COURT: Well, I'm going to sustain the  
11 objection. I think you can go through her opinions. It  
12 seems to me that what you've cited is perhaps a basis for  
13 her to reach a conclusion that Pradaxa was safe and  
14 effective.

15 But if she doesn't say that directly in her report, I  
16 think you've got to wade through the particulars that she  
17 did say in her report, and you can use those.

18 MR. LEWIS: I can show Your Honor the general  
19 report then? Because that's going to -- I mean, that's  
20 going to inform Your Honor on her specific opinions on the  
21 drugs themselves.

22 THE COURT: You know, probably not because  
23 honestly if she provided that opinion and had that  
24 discussion in her general report, she should have included  
25 it here.

1 And when I see a general report from an expert and then  
2 a case specific report, the case specific report has to  
3 include the specifics opinions that the expert is going to  
4 testify to about the potential in the case.

5 So her general opinions about something may not be  
6 applicable in the case specific report. If, if it's -- if  
7 she doesn't tie them together in her case specific report, I  
8 don't think she can come in and testify about the general  
9 things.

10 But you asked her more than just generally. You said,  
11 "Is Pradaxa safe and effective for Mrs. Knight?" And I  
12 don't see that she offered that specific opinion.

13 I see that you asked her about her course and what went  
14 right or what went wrong or what didn't go wrong. And I  
15 think you can do that. But I think you're going to have to  
16 confine it to, to the way she addressed it in the report and  
17 not now include some general all-encompassing opinion that  
18 she didn't state in her report.

19 MS. JONES: But we're allowed to go through with  
20 her the specific instances that she views as signaling that  
21 Pradaxa was an effective and safe medicine for Mrs. Knight?

22 THE COURT: Absolutely.

23 MS. JONES: Okay.

24 MR. LEWIS: Okay.

25 THE COURT: Sorry if it complicates your

1 examination, but I think that's the way you have to address  
2 it, the way she did in her report.

3 MR. LEWIS: Okay.

4 (Bench conference concluded)

5 THE COURT: All right. I'm going to sustain the  
6 plaintiffs' objection and direct defense counsel to reframe  
7 the question that he's about to ask of the expert.

8 BY MR. LEWIS:

9 Q. Dr. Shami, one of the things that I asked you to do was  
10 to make a determination as to the cause of Mrs. Knight's GI  
11 bleed that she experienced in May of 2013. Were you able to  
12 do that?

13 A. I was.

14 Q. Okay. And did you make a determination as to whether  
15 or not in connection with Mrs. Knight's GI bleed she was  
16 over-anticoagulated on Pradaxa?

17 A. So we don't use that word usually in clinical medicine.  
18 We can use supratherapeutic, subtherapeutic.

19 Over-anticoagulated is a word that assumes that there is  
20 actually a range for Pradaxa that has been defined. So, no,  
21 I, I mean, I don't think she was over-anticoagulated.

22 Q. And as part of your review, did you look at  
23 Dr. Ashhab's view that if Mrs. Knight had been on warfarin  
24 instead of Pradaxa that she would not have suffered a bleed?

25 A. I saw that.

1 Q. Do you agree with that?

2 A. I absolutely do not agree with that whatsoever. I  
3 don't think anybody can say that if she were on a different  
4 blood thinner, the outcome would have been different,  
5 especially when we know what bled. There's an AVM or, you  
6 know, arteriovenous malformation. It's clear that Dr. Huh  
7 saw it. We know it was bleeding.

8 Q. Okay. And the last thing I asked you to do was to look  
9 into whether either Mrs. Knight's May, 2013, GI bleed or  
10 Pradaxa led to her passing in September of 2013. Were you  
11 able to do that?

12 A. I did look at that.

13 Q. And Dr. Ashhab suggested that Pradaxa or the GI bleed  
14 contributed to Mrs. Knight's passing. Do you agree with  
15 that?

16 A. I disagree with that. Would you --

17 Q. Sure, if you want to briefly.

18 A. So a few things is her repeat hospitalizations before  
19 and after that. The majority of cases were due to heart  
20 issues. So her course after that GI bleed was not very  
21 different than her course in 2008 and 2011.

22 Q. Okay. We're going to talk more specifically about each  
23 of those opinions and how you came about getting to them.  
24 But let's just back up for a couple of seconds and again  
25 talk a little bit about your education, your employment, and

1 your training.

2 So let's first start with where you went to undergrad.

3 A. Colgate University which is a small liberal arts school  
4 in upstate New York.

5 Q. And what was your degree?

6 A. Biology.

7 Q. And then did you go on to medical school after that?

8 A. I did.

9 Q. And where was that?

10 A. The University of Virginia.

11 Q. Okay. And after -- and how long does that take  
12 typically?

13 A. It takes four years.

14 Q. Okay. And after that, did you do a fellowship?

15 A. So after that, I did an internship and residency in  
16 internal medicine. And that was also at the University of  
17 Virginia. And then -- so that was three years. And then I  
18 did another three years of training as a gastroenterology  
19 fellow at the University of Virginia.

20 Q. Okay. And what does it mean to be a fellow?

21 A. So what a fellow means is, first of all, you need to  
22 have completed your internal medicine education. And you  
23 need to eventually get board certification in internal  
24 medicine.

25 After that, then you can choose a track in internal

1 medicine. It can be cardiology. It can be  
2 gastroenterology. It can be nephrology, or kidneys. So  
3 there's numerous different paths you can potentially go to.  
4 And I chose gastroenterology. So I did three years of  
5 gastroenterology training.

6 Q. And did you eventually become Board Certified in  
7 gastroenterology?

8 A. I did. So after my GI fellowship, I actually went to  
9 the University of Chicago and did an additional year of  
10 procedures, and then came back on faculty and then got my --  
11 after that year, I did get Board Certified.

12 Q. And is that something that has to be renewed or kept  
13 up-to-date over time?

14 A. It is. So what we do is we have these maintenance of  
15 certification points that we have to take, and they are  
16 certain courses. So you have to do that and you have to  
17 renew. So not only do you have to do course work, and it  
18 can be through conferences, but in addition to that you have  
19 to take a test every 10 years. And, so, I've renewed once.

20 Q. So you're currently Board Certified or you've been  
21 recertified and you're under that certification at this  
22 time?

23 A. Correct, in gastroenterology.

24 Q. Okay. Now, are there some key organizations that folks  
25 in your space typically join, gastroenterologists, things

1 like that where they learn maybe from others or go to  
2 training programs or seminars?

3 A. Yes. So there are three major societies in  
4 gastroenterology. Those are the American College of  
5 Gastroenterology, the American Society for Gastrointestinal  
6 Endoscopy, and the American Gastroenterology Association.

7 Q. And do you have any leadership positions on any of  
8 those organizations?

9 A. So I do. I work -- because the American Society for  
10 Gastrointestinal Endoscopy focuses on endoscopy, scoping  
11 procedures, and that's my specialty and my interest and  
12 passion, I actually am on the leadership of that society.

13 Q. Now, how many folks are on the leadership or the board  
14 of that society?

15 A. So 10 of us are.

16 Q. And how big is the group that the board oversees?

17 A. It's almost 15,000 gastroenterologists.

18 Q. And what kinds of things do the folks on the board like  
19 yourself end up doing for the greater population of  
20 membership?

21 A. So we represent the gastroenterologists in legislation  
22 in terms of reimbursement. We also are very crucial in  
23 coming up with appropriate guidelines for patient care such  
24 as, you know, GI bleeding, you know, what's the next test to  
25 come up with an algorithm. So we foresee that. We actually



1 basically run anything you would imagine with a, with a  
2 society in general.

3 Q. Now, I also noticed from your resume that you've had a  
4 number of publications in the field of gastroenterology; is  
5 that correct?

6 A. That is correct.

7 Q. A few dozen maybe. I didn't count them all up. But  
8 what generally are the topics that you've published on?

9 A. Yeah. The majority of my topics are on, you know,  
10 complex endoscopic procedures and outcomes; so, you know,  
11 anything to do with endoscopy.

12 I do a lot of internal ultrasound biopsies. So if  
13 somebody has pancreatic cancer, I do a biopsy or lung cancer  
14 I do it from inside out essentially.

15 I do a lot of resections. I remove a lot of lesions  
16 that patients would normally go to surgery for. I do a lot  
17 of -- I do actually a lot of GI bleeding only because often  
18 times people are referred to us because they have a bleed  
19 that can't necessarily be stopped elsewhere. So anything,  
20 you know, endoscopy related is kind of what I focus on and I  
21 publish.

22 Q. Do you also present at conferences where other  
23 gastroenterologists are there to learn more about the signs  
24 and treatment, diagnosis of things that are of interest?

25 A. I do. I do a lot of teaching. I go to different

1 institutions. I was just at Northwestern. I was just in  
2 Guayaquil, Ecuador. A lot of what I do is either I'm doing  
3 the procedure, talking to the audience and the panel.  
4 They're asking me questions while I'm actually doing the  
5 procedure. It's as stressful as being in court.

6 And then I also do a lot of lecturing. So, you know, I  
7 do a lot of post-grad, we call post-graduate courses. And  
8 those are anywhere between, you know, two to three thousand  
9 gastroenterologists in the audience. So -- and I enjoy it.  
10 I enjoy teaching.

11 Q. And do you sometimes get invited and then do procedures  
12 while you're talking through the procedure so other folks  
13 can see how to do maybe a treatment of a GI bleed or  
14 something along those lines?

15 A. Absolutely. I just, again, in, in August was in  
16 Ecuador and I did, I did cases. Needless to say, it's, you  
17 know, it's stressful. And you feel a lot of responsibility  
18 because you are doing procedures on people that, you know,  
19 need them but may not necessarily be close-by all the time.  
20 So --

21 Q. Now, you're getting paid for your time here in court  
22 today; is that correct?

23 A. I am.

24 Q. And that's approximately \$600 an hour for your time?

25 A. Yes, here.

1 Q. Here today. And then in other work that you've done in  
2 this case, you've gotten paid about \$450 an hour; is that  
3 right?

4 A. That is correct.

5 Q. Okay. And this is your first time in court; right?

6 A. It is.

7 Q. All right. With respect to the work that you did in  
8 this case, did you bring -- and this may seem obvious. But  
9 did you bring all of the training and the experience and the  
10 things that you've learned and taught other people to bear  
11 here when you were forming your opinions?

12 A. I did.

13 Q. And let's talk about what else you did besides relying  
14 on your training and experience in the clinical practice and  
15 teaching. Did you review some materials in this case?

16 A. I did.

17 Q. Did you review Mrs. Knight's medical records, for  
18 instance?

19 A. Absolutely, yes.

20 Q. Did you review the depositions of the treating  
21 physicians and other folks who worked with Mrs. Knight?

22 A. I did.

23 Q. All right. And did you find that in looking at the  
24 medical records that there were any gaps in the history of  
25 Mrs. Knight's warfarin experience?

1 A. So in 2008 there are, there are sizeable gaps in sort  
2 of her hospital course and, and what had happened to her  
3 warfarin, like why, you know -- before what I feel to be her  
4 GI bleed in November of 2008. She was off the warfarin for  
5 a while. And, so, it's kind of unclear what, you know,  
6 prompted that before that 2008 hospitalization.

7 So, yes, there were gaps in her medical record.

8 Q. And then as well I gave you -- I asked you to look at  
9 Dr. Ashhab's testimony from the trial as well.

10 A. You did.

11 Q. And you looked at that as well?

12 A. I did.

13 Q. Okay. And I might ask you some questions about that.

14 Before we get into specific things related to Mrs.  
15 Knight, it might be helpful to do maybe a high level  
16 tutorial on gastroenterology.

17 I'll call it Gastroenterology 101. And do we have a  
18 demonstrative that we could pull up for that?

19 Doctor, I think maybe just describe a little bit for  
20 the jury what does gastroenterology entail and sort of where  
21 this fits into this case.

22 A. Sure. So you can see on this patient who has an  
23 extremely long neck, you can see that there is -- this is  
24 the digestive tract. So it involves the luminal tract which  
25 is the esophagus here. And then you've got the stomach.

1 And then after the stomach, that's the upper GI tract. So  
2 this is the upper GI tract. Okay? And then this is the  
3 colon. So you can see the colon here. Okay?

4 So that is what we usually cover with standard  
5 endoscopy. All the rest of the gut, which is the small  
6 bowel, is in between that. And when we do endoscopy, most  
7 of the times we're not covering that area.

8 So my specialty has to do with this as well as the bile  
9 ducts which are here, the pancreas, and, and liver. So  
10 anything that has to do with digestion, both the lumen as  
11 well as the organs that help with digestion. So we can go  
12 to the next slide.

13 So looking at this figure -- and I need to erase if I  
14 can -- I'm not sure how to erase this.

15 Q. Is there a "clear" in the bottom right-hand corner?

16 A. No. So if we can -- perfect. Thank you.

17 So if you look here, I just want you to keep in mind  
18 the person, or this figure is looking at you. So what you  
19 would notice, you know, looking at it, left is actually  
20 right because, again, the figure is looking at you if that  
21 makes any sense. It's facing you.

22 And these are the labels of the different parts of the  
23 GI tract. You can see the esophagus, which is our  
24 swallowing tube. We've got the stomach which collects the  
25 food. And anything that you see in that blue/purple color

1 is what we cover with the upper endoscopy.

2 Then this is the small bowel here, the duodenum we call  
3 it, the first part of it. Again, this is the small bowel  
4 and this is the colon right here (indicating).

5 And so, again, since it's facing you, anything on your  
6 right is the left of the patient. And anything to the left  
7 is the right of the patient if that makes any sense. So  
8 that is the GI tract close-up.

9 If we can go to the next figure.

10 So this is an upper endoscopy or EGD. I'm sure you've  
11 heard of this over the last few days. When we do an upper  
12 endoscopy, we take a scope with a camera. We go down the  
13 mouth and obviously the patient is sedated. We look at the  
14 esophagus, the stomach, and small bowel. And that is the  
15 amount of territory that it covers.

16 So you can see the majority of the GI tract is not  
17 looked at. Okay?

18 And then if we can go to the next, this is the  
19 colonoscopy. We're looking at the large intestine. And  
20 that's how far it covers. So it goes all the way to the end  
21 of the large intestine, but does not again cover the small  
22 intestine.

23 So when we're doing an upper endoscopy and lower  
24 endoscopy or colonoscopy, this is what we mean.

25 Now, one thing I want to emphasize is when you're

1 having a GI bleed, it can be like a cut where you bleed red.  
2 Okay. So we all, you know, we bleed red when we're cut.

3 But in the GI tract sometimes the blood, if it's  
4 digested, can be dark or black. So that's why as  
5 gastroenterologists we keep asking, "Have you had red blood?  
6 Have you had dark blood? Have you had black stools?"

7 Okay? So that's extremely important to keep in mind.  
8 So when we ask that as gastroenterologists, there is a  
9 reason for that.

10 So if we can go to the next slide.

11 So this is a colon you can see there. And there are  
12 many reasons why people can bleed. You know, this right  
13 here is a depiction of an AVM. It has a fern-like pattern  
14 if you look at it. And these are little vessels that come  
15 up to the surface of, of the lumen. Okay. They're  
16 irregular.

17 And the other thing about them is the walls are really  
18 fragile. Okay? We see this all the time in GI. They're a  
19 major reason for bleeding, especially in elderly folks.  
20 Okay?

21 They're managed very readily. But you can see -- and  
22 they can be actually anywhere in the GI tract. But if  
23 they're in the colon, they're usually on that right side of  
24 the colon as you can see here.

25 Q. And let me ask you just for a second, the jury's heard

1 a little bit about AVMs or arteriovenous malformation. Did  
2 I get that close?

3 A. That was perfect.

4 Q. Okay. And can those occur in folks who are on no  
5 medications at all?

6 A. Absolutely. We see it all the time.

7 Q. And can they occur in folks who have anticoagulant  
8 medicines that they're taking?

9 A. Absolutely.

10 Q. And does it matter what anticoagulant medication that  
11 the folks are taking?

12 A. No.

13 Q. You've seen bleeds in your practice with folks off --  
14 without any medicine or different anticoagulants?

15 A. Correct.

16 Q. Xarelto, Pradaxa, warfarin, or Coumadin, all of the  
17 above. Would that be fair?

18 A. That is totally fair.

19 Q. Okay. So let's talk a little bit more about -- and I  
20 think you were getting into this -- sort of how you go about  
21 figuring out when someone presents to you with a suspected  
22 bleed what they have and how to treat it.

23 A. So when somebody presents, the first thing you're going  
24 to do is you're going to ask them questions. So you're  
25 going to take a history; when did the GI bleed start, you



1 know, what are you having? Are you vomiting blood? Because  
2 if they're vomiting blood, you would think it's from that  
3 upper GI tract.

4 And if we could go back a couple, it would be --  
5 usually if they vomit blood it will be from -- one more --  
6 somewhere in that blue -- one -- I'm sorry -- yeah, so  
7 somewhere in that blue/purple area if they vomit up blood.  
8 And when I say blood, again, I mean dark vomitous. So black  
9 or dark is blood or red. Okay? So that's, that would be  
10 from the upper GI tract.

11 And then you ask them, "Have you passed red stools or  
12 dark stools?" So that's the next thing. You always want to  
13 look at their vital signs, you know; are they stable, is  
14 their blood pressure okay, is their heart rate okay.  
15 Because if it's not, if it's a really severe bleed, we will  
16 actually manage them in the intensive care unit.

17 Q. Okay. And with respect to looking for an AVM that may  
18 be in the colon, how would you go about figuring out whether  
19 that may be the case and how would you go about treating  
20 someone that had that that was bleeding?

21 A. Yeah. So if, if we're suspecting an AVM in the colon,  
22 the way we would do it is do a colonoscopy. So the first  
23 thing we would do is have somebody drink that great old jug  
24 of GoLytyl usually is what we use.

25 And then we go ahead with the camera and the scope and

1 we look at the entire colon. We want to look really  
2 carefully because they can sometimes be missed.

3 When we see the actual AVM, what we can do is we can  
4 treat it. So we can either, you know, we can inject it and  
5 put a little heat on it. We can clip it. We can put a  
6 rubber band around it.

7 So we have options on how to treat these AVMs.  
8 They're very -- again, we see them all the time. They're  
9 straightforward usually to treat, especially in the colon.

10 Q. And as far as the timing of treatment, for most of the  
11 times that you have to treat an AVM -- and, by the way, can  
12 an AVM bleed when someone is not on an anticoagulant  
13 medication?

14 A. Absolutely, yes.

15 Q. And if they are on an anticoagulant medication,  
16 obviously a bleed could occur as well?

17 A. Absolutely.

18 Q. And if you had to describe what you would think from  
19 your clinical experiences a successful treatment of an AVM  
20 bleed, how would you describe that? What characteristics  
21 would there be about a successful treatment?

22 A. If we can find the actual AVM bleed, once we see the  
23 lesion, it's close to 100 percent. Sometimes AVMs can be a  
24 little tricky because they will be in the small bowel. And  
25 as we kind of stated, in that small bowel area it's kind of

1 tricky to get to. It takes special endoscopic equipment to  
2 get to that area.

3 Q. And as far as the timing of the hospital stay, what  
4 would you say a successful treatment of an AVM bleed would  
5 be? What would the outcome be as far as timing a hospital  
6 stay and how long someone took to kind of have the bleeding  
7 stopped?

8 A. Sure. You know, we would consider it successful if you  
9 can stop it within the first day or so. And usually  
10 hospitalizations aren't very long for AVM bleeds, especially  
11 if we can find them and treat them. It should only be a few  
12 days.

13 Q. Okay. Now, the jury has heard in this case the fact  
14 that anticoagulant medications across the board can increase  
15 the risk of a bleed and also affect the amount and the  
16 ability to stop a bleed. And are you aware of that from  
17 your experience as well?

18 A. Yes. So anticoagulants can definitely, you know,  
19 increase the amount of a bleed.

20 Q. And from your experience, is that something that's  
21 well-known by folks who treat patients for bleeds like  
22 yourself?

23 A. Absolutely.

24 Q. And with respect to the special circumstance of someone  
25 who presents, say I present with a suspected bleed and I'm

1 on an anticoagulant medication, what's one of the first  
2 things that you're going to do?

3 A. So we usually will hold. So obviously we'll assess you  
4 like I described before, but we would hold that  
5 anticoagulant. And then we would go ahead and try to, try  
6 to find the reason for the bleeding.

7 We're very fortunate now in that we have tools that we  
8 can use. And when I say that, the last 15 or so years we  
9 have what are called clips. They're little metallic clips  
10 that literally can go onto the lesion and we close it  
11 through the scope and they're very easy to use. And you can  
12 do that in somebody who's anticoagulated and it makes it  
13 very easy.

14 Q. And how soon after would you start someone back on an  
15 anticoagulant medication if you treated them successfully  
16 for a bleed?

17 A. So I personally would look to see what risk factors the  
18 patient has for clotting; you know, have they had a stroke  
19 before, have they had clots before.

20 You really want to assess their risk of having those  
21 problems because if you look at bleeding versus clot,  
22 stroke, usually clot and stroke is very tough once you have  
23 a big stroke to recover from that.

24 So bleeding usually we can do something for. We can  
25 treat it. So I really, really -- you know, we all as

1 physicians favor, you know what, let's start this because we  
2 don't want people to have strokes. We don't want people to  
3 have clots.

4 But in all fairness, often times if I have any  
5 question, it will be in consultation with a cardiologist or  
6 the physician who put the patient on the anticoagulant.

7 Q. Fair enough. All right. Have you told us -- have you  
8 kind of given your Gastroenterology 101 with us and we'll  
9 move on to Mrs. Knight's scenario or is there anything else  
10 that you wanted to make sure that the jury understood before  
11 we did that?

12 A. No, I think, I think we're good. Thank you.

13 Q. Thank you for that.

14 One of the things that you did as your, part of your  
15 work in this case was to look at Mrs. Knight's experience  
16 while she was on the warfarin medication; is that right?

17 A. That is correct.

18 Q. And you made -- you drew some conclusions about  
19 specific medical events that were associated with her  
20 experience on warfarin. Is that fair to say?

21 A. I did.

22 Q. Now, are you familiar in your practice generally with  
23 the medicine warfarin?

24 A. Absolutely.

25 Q. Have you treated patients that have had bleeds while on

1 warfarin?

2 A. All the time.

3 Q. As part of your training and experience and knowledge,  
4 are you familiar with the risks that are associated with  
5 warfarin?

6 A. I am.

7 Q. Could you outline just at a high level some of the  
8 risks that are associated with warfarin?

9 A. Sure. The, you know, major risk, obviously you're  
10 giving somebody an anticoagulant, so, you know, the major  
11 risk is bleeding with warfarin.

12 Q. And with respect to sort of digging in a little deeper  
13 into that issue, what about drug interactions with warfarin?  
14 Is that something that you've considered as part of your  
15 practice?

16 A. Yes. So there is a long list of drug interactions  
17 because it is metabolized in the liver. So there are many  
18 drugs that can interact with warfarin.

19 The other thing about warfarin, again, is you've got to  
20 avoid -- the way warfarin works is it's a Vitamin K  
21 antagonist. So if you -- you want to avoid foods that are  
22 high in Vitamin K, so leafy vegetables. There's -- leafy  
23 vegetables like lettuce. There's -- spinach.

24 So there's a lot of things that patients find difficult  
25 to comply with because we're not talking about a day. We're

1 not talking about dietary restriction for three days. We're  
2 talking for the rest of the course on that drug.

3 Q. Right. And let, let me focus first on drug  
4 interactions and then I'll get into the diet. But with  
5 respect to drug interactions, if I have a lot of medications  
6 that I'm taking that are metabolized in the liver, is that  
7 going to affect how my warfarin reacts inside my body?

8 A. Yes.

9 Q. Okay. And which way will it affect it?

10 A. Either way.

11 Q. So it depends on the medications that I'm taking?

12 A. That is correct.

13 Q. One could inhibit, in other words, make warfarin sort  
14 of more effective or make my blood thinner. Is that fair?

15 A. That is correct.

16 Q. And then some medications might make my blood, for lack  
17 of a better term, thicker?

18 A. That's correct.

19 Q. Which would increase my stroke risk; right?

20 A. Yes.

21 Q. And that has to be taken into account by physicians who  
22 are monitoring patients on warfarin?

23 A. Correct.

24 Q. And then with respect to dietary restrictions, same,  
25 same effect. If I eat too many green, leafy vegetables over

1 the course of a week, that may make my warfarin less  
2 effective because it's going to make my blood a little  
3 thicker with the Vitamin K. Is that fair to say?

4 A. That is correct.

5 Q. The jury's heard some about therapeutic range with  
6 warfarin. Are you familiar with that phrase as it's used  
7 with warfarin treatment?

8 A. I am.

9 Q. Okay. And could you describe for the jury a little bit  
10 about what that means?

11 A. Sure. We touched a little bit about -- on this  
12 earlier. As physicians, we check an INR. It's how thin the  
13 blood is. And that is specific to or pertains to warfarin  
14 or Coumadin.

15 And in order for warfarin to work well and to avoid  
16 clots and strokes, you want that INR level between 2 and 3.

17 Q. Now, as part of your work in this case did you happen  
18 to look at Mrs. Knight's medical records, and specifically  
19 the various INR readings that she has had over time, had had  
20 over time with, while she was on warfarin?

21 A. I did.

22 Q. Okay. And did you happen to sort of plot those out  
23 over time?

24 A. I did.

25 Q. All right. If we could have the demonstrative, please,



1 of the fluctuating. And the jury has seen this.

2 MR. CHILDERS: Judge, could we have another  
3 sidebar?

4 THE COURT: Yes.

5 (Bench conference on the record)

6 MR. CHILDERS: The question just asked was, "Did  
7 you happen to plot those out over time?" She clearly never  
8 gave me an exhibit showing she plotted these things out over  
9 time.

10 MR. LEWIS: Well, she reviewed the INR levels.  
11 They're all in the medical records that were provided. She  
12 reviewed each one of them and worked with us to make sure  
13 that they were plotted in that demonstrative that the jury  
14 has seen over and over and over.

15 THE COURT: Well, rephrase your question and  
16 phrase it that way so that it doesn't suggest that she  
17 prepared the chart.

18 MR. LEWIS: Okay. I can do that.

19 THE COURT: And then if you like, I can instruct  
20 the jury that this chart is a demonstrative exhibit only and  
21 the extent -- the jury shouldn't treat it as evidence. It  
22 can be used, but it's up to the jury to decide whether or  
23 not it's supported by the underlying records.

24 MR. CHILDERS: That would be great, Your Honor. I  
25 just wanted to make sure they didn't think she made the

1 chart because she didn't.

2 THE COURT: Okay.

3 MR. LEWIS: She assisted on it, but whatever.

4 It's not worth arguing about.

5 THE COURT: It did sound a little bit like that.

6 MR. LEWIS: While we're at sidebar, because the  
7 summary is not coming in, I'm putting in what's behind the  
8 summary which is all of the medical records that show the  
9 INR levels. This is what he wants me to do, so I'm going to  
10 put that stack of medical records in. It reflects the INR  
11 levels that she reviewed. I should be able to do that.

12 MR. CHILDERS: I thought it already came in.

13 THE COURT: Well, it's part of the chart so  
14 it's -- I've said that the underlying medical records are  
15 sufficiently authenticated to be independently admissible.

16 MR. CHILDERS: I think they've already been  
17 admitted as part of the big record anyway.

18 THE COURT: Separately from that?

19 MR. CHILDERS: Yes.

20 THE COURT: Well, either way you're free to use  
21 the exhibit.

22 MR. LEWIS: Okay.

23 THE COURT: Put them in a third time.

24 (Bench conference concluded)

25 THE COURT: All right. Counsel is about to use a

1 chart. I think this was used earlier in the examination of  
2 witnesses.

3 I just want to remind the jurors that charts like this  
4 are what we call demonstrative aids, meaning they're merely  
5 used -- prepared by the lawyers and used to help explain and  
6 summarize evidence.

7 This chart and similar demonstrative aids are not  
8 evidence and you can only use or rely upon the chart to the  
9 extent that you find it is supported by the underlying  
10 evidence.

11 So when somebody on either side has a chart that  
12 purports to summarize medical records or medical history,  
13 it's not the chart that is the evidence. It is the  
14 underlying records.

15 And, so, if there's a difference between underlying  
16 records and the chart, obviously you should not consider the  
17 demonstrative aid accurate. If there isn't any difference,  
18 then it is a demonstrative aid to help summarize the chart.

19 With that, do you want to restate your questions and  
20 get into this chart?

21 MR. LEWIS: I do, Your Honor. Thank you.

22 BY MR. LEWIS:

23 Q. Dr. Shami, so with respect to the demonstrative that  
24 I'm going to show you, that was prepared by trial graphics  
25 folks that are working with me; right?

1 A. That is correct.1178

2 Q. Okay. What you did is you reviewed the underlying  
3 medical records that are associated with those INR readings;  
4 is that right?

5 A. Absolutely.

6 Q. And you looked to make sure that that was consistent  
7 with your review of the medical records?

8 A. Absolutely.

9 Q. Okay. So if we could show the demonstrative, so, Dr.  
10 Shami, tell us what is significant about what you're seeing,  
11 what the jury is seeing right here in this demonstrative  
12 exhibit.

13 A. So on the left you can see the numbers and you can see  
14 it says "INR scale." And what we're aiming for for patients  
15 is an INR within that yellow range, so between 2 and 3  
16 because we know that is the range where if it's, again, if  
17 it's too high, your chances of bleeding goes up. If it's  
18 too low, then we're not serving the, the purposes of trying  
19 to avoid a stroke or a heart attack or, or any sort of clot.

20 And what you can see here, the INRs have been plotted  
21 out. And anything that is outside that yellow bar, so  
22 either above it is too high. Below it is too low.

23 You can see about -- and I think I actually counted.  
24 It's about, less than 50 percent of the time is her INR  
25 within the desired range.

1           So, again, this puts her at risk of either bleeding or  
2 clotting. And it's not an ideal medication in somebody who  
3 can't keep that range. And it's not a fault. It's just  
4 very difficult in some patients to keep it within that ideal  
5 range.

6       Q.    And I wanted to ask you about that, what you just said  
7 at the end which is it's, it's not the patient's fault  
8 necessarily that this medication is working this way. Is  
9 that fair?

10     A.    That is correct. It is absolutely not the patient's  
11 fault.

12     Q.    And it's not necessarily the doctor's fault either?

13     A.    No.

14     Q.    Is that fair?

15     A.    That is fair.

16     Q.    Okay. Would it be fair that this just sometimes can  
17 happen with warfarin patients?

18     A.    Yes.

19     Q.    And would you agree that this isn't a safe way to be on  
20 warfarin?

21     A.    Yes.

22               MR. LEWIS: Now, Your Honor, I'm going to move  
23 into admission the actual medical records that back up the  
24 demonstrative as 9009-S without the summary chart that's at  
25 the beginning of that exhibit.

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1 THE COURT: All right. Does plaintiff have any  
2 objection?

3 MR. CHILDERS: To the medical records, Your Honor?

4 THE COURT: Yes.

5 MR. CHILDERS: No objection.

6 THE COURT: All right, the medical record will be  
7 admitted. And that's 9009-S without the chart.

8 MR. LEWIS: Correct.

9 (Exhibit Number 9009-S admitted into evidence.)

10 BY MR. LEWIS:

11 Q. And, Dr. Shami, --

12 MR. LEWIS: In fact, Your Honor, if I may, I have  
13 the exhibits that I'm using with the witness. May I  
14 approach to make sure the Court has those?

15 THE COURT: Yes.

16 MR. CHILDERS: I'm sorry, Your Honor. I  
17 understood 9000-S to be the chart.

18 THE COURT: Well, what he's now moving is Exhibit  
19 9009-S consisting only of the underlying medical records  
20 that were part of the originally tendered exhibit. The  
21 chart is withdrawn.

22 MR. CHILDERS: Understood. Thank you, Your Honor.

23 THE COURT: Okay.

24 BY MR. LEWIS:

25 Q. And, Dr. Shami, do you have that exhibit in front of

1 you?

2 A. I have 900 --

3 Q. -- 9-S?

4 A. Uh-huh.

5 Q. Okay. And if we just look at -- if you go to the -- I  
6 just want to double-check a couple of these references just  
7 to make sure.

8 A. Sure.

9 Q. If we go to 9009-172 you'll see that there are Bates  
10 numbers at the bottom center of each of the documents. Do  
11 you have that page?

12 A. I do have that page.

13 Q. And you see that there's an INR reading of 1.9?

14 A. I do.

15 Q. From -- looks like April of 2007?

16 A. Yes. It's April 4th, 2007, correct.

17 Q. And if we look at the chart, we see in April --  
18 sometime in early April of 2007 there is -- the INR reading  
19 is 1.9, so it's just out of range, just below 2.

20 A. That is correct.

21 Q. And that's plotted on this particular demonstrative; is  
22 that right?

23 A. Yes.

24 Q. And did you spot-check some of the INRs for this  
25 particular demonstrative?

1 A. I did.

2 Q. Okay. With respect to warfarin patients that you've  
3 seen in your experience, when there is a bleed event with  
4 someone who maybe has an AVM -- let's just talk about an AVM  
5 because that's the subject matter here -- does it matter  
6 whether their INR levels are within a therapeutic range or  
7 not when it comes to your treatment of a bleed event?

8 A. So that's a good question. What I tend to do is --  
9 first thing I would do is stop the warfarin. If the INR is  
10 really, really high and they're bleeding so briskly that  
11 they're in the ICU and I'm having trouble kind of keeping up  
12 with their blood counts, despite transfusions, then I would  
13 make that decision to potentially reverse the warfarin.

14 So I can give somebody Vitamin K, although Vitamin K  
15 takes hours, or fresh frozen plasma is usually what we use.  
16 Again, it has its side effects, especially in people with  
17 heart failure. There's a lot of volume. But that's what we  
18 would do.

19 Q. When you're treating a bleed with warfarin versus a  
20 bleed with maybe a NOAC like Pradaxa --

21 A. Uh-huh.

22 Q. -- oral anticoagulant, is there a difference from your  
23 experience in the timing of when you stop the medication and  
24 the ability to control the bleeding?

25 A. Yes. So the half-life -- so the amount of time it



1 takes for the drug to come out of the body is a lot shorter  
2 for the NOAC drugs than it is for warfarin. And that's  
3 predominantly the reason why if you have somebody with an  
4 extremely severe bleed that you cannot control that we  
5 reverse it.

6 So the NOACs, if you stop it, by the next day or two  
7 days from then, it should be out of the patient's system.

8 But with warfarin we wait five to seven days before  
9 doing an elective procedure. Obviously, if it's an urgent  
10 procedure, we'll do it right away. So there is a  
11 difference.

12 Q. And with respect to this therapeutic range or being out  
13 of a therapeutic range, would there be -- would it be fair  
14 to say that someone perhaps with an INR level of 8 is going  
15 to be more difficult to control from a bleeding perspective  
16 than someone in the therapeutic range?

17 A. Potentially. Again, if we, if we find the lesion --  
18 it's all about the lesion. If we can find the lesion that's  
19 bleeding, we can clamp it. We have ways now to treat  
20 patients on anticoagulation.

21 Q. Okay, all right. I'm finished with that demonstrative.

22 Did you as part of your work also look into the use of  
23 warfarin in Mrs. Knight's experience and, and whether she  
24 was on it and off it at various points in time?

25 A. I did.

1 Q. Okay. And, in particular, in 2008 do you recall an  
2 instance where she had gone off warfarin because she didn't  
3 want to get her levels checked, going to the physician to  
4 get her levels checked?

5 A. Again, this is a spotty area in the chart. But, yes,  
6 she was off of it in September, 2008. And the way I know  
7 that is that there's a note from her cardiologist,  
8 Dr. Haberman, stating that she should be back on an  
9 anticoagulant.

10 Q. And let's take a look at that. This has been admitted  
11 into evidence as 9007-A already. And if you look at that in  
12 your notebook, the first page is just the certification of  
13 medical records. But if we could see 9007-A-8, is this the  
14 record that you were referring to?

15 A. It is.

16 Q. And this is a note from Dr. Haberman from September of  
17 2008; is that right?

18 A. That is correct.

19 Q. And, in particular, there's -- as you scroll down, I  
20 believe the note is referring to an impression. Obviously,  
21 there's a history of stroke. Is that what you're referring  
22 to when, when you're talking about kind of the records  
23 before this time not being available?

24 A. Yeah. It's unclear -- exactly. I mean, we don't have  
25 the records prior to this point.

1 Q. But a doctor is noting somewhere along the way, Mrs.  
2 Knight had had a stroke at some point?

3 A. Oh, yeah, it's clear that she's had a stroke. They  
4 actually even say she's had left-sided weakness from the  
5 stroke.

6 Q. Okay. And Dr. Haberman is noting, if we go to the  
7 recommendation and we scroll just a little bit further, what  
8 is -- if we highlight number one, Mrs. Knight absolutely  
9 needs to get back on her Coumadin. That's the same word for  
10 warfarin. Right?

11 A. Correct.

12 Q. Because her risk of having another stroke with her  
13 chronic AFib, atrial fibrillation, is high. And, so, he's  
14 putting her -- he's recommending that she go back on  
15 Coumadin. Is that correct?

16 A. That is correct.

17 Q. And then there's a note on the next page related to  
18 Plavix. Do you see that?

19 A. I do.

20 Q. Okay. And what does that indicate to you as someone  
21 who is familiar with the concept of Plavix, other  
22 anticoagulants?

23 A. I think his concern here is having triple therapy,  
24 having all three on board. So, again, it says, "Discontinue  
25 Plavix to prevent bleeding from concomitant," which means at

1 the same time use, "aspirin and Coumadin therapy."

2 So then, again, the physicians are very conscious of  
3 bleeding risks versus stroke and clot risk. So this is in  
4 their assessment the entire time you can tell looking at  
5 medical records.

6 Q. And would it be fair to say that at least at this point  
7 in time, Dr. Haberman is concerned about using warfarin with  
8 Plavix and aspirin for Mrs. Knight?

9 A. Yes.

10 Q. Because of the bleed, the potential for a bleed?

11 A. That is correct.

12 Q. Okay. And is that -- and, by the way, is that  
13 something that's sort of -- do you understand what triple  
14 therapy is? Have you had patients present with bleed events  
15 while on triple therapy?

16 A. Yes.

17 Q. And that would be basically three different types of  
18 anticoagulant or anti-platelet medication. Would that be a  
19 way to characterize it?

20 A. That is correct?

21 MR. CHILDERS: Your Honor, I just want to  
22 interpose an objection to leading here. He's been leading  
23 her over and over and I would just ask him not to lead.

24 THE COURT: All right. Try to avoid leading.

25 MR. LEWIS: Sure.

1 BY MR. LEWIS:

2 Q. Doctor, did you look into -- and I'm finished with  
3 that. Thank you.

4 Did you look into whether or not there may have been a  
5 bleed event with Mrs. Knight while she was on warfarin?

6 A. I did. So in November, 2008, she had presented to the  
7 hospital with dark stools and, and, and some weakness. And  
8 if you look at her blood levels, her blood levels went down  
9 and she had dark stools. So the physicians were concerned  
10 about a GI bleed and they actually consulted a  
11 gastroenterologist.

12 Q. So let's take a look at a couple of the records that  
13 you had pointed out to me. This would be in 9007-A also.  
14 And start first with Page 19 and the history of the present  
15 illness. Do you have that in front of you, Doctor?

16 A. I do.

17 Q. And can you describe for the jury what's significant  
18 about what's being discussed here in this note?

19 A. Sure. If you look at the chief complaint, and that's  
20 usually why the patient comes to medical attention at that  
21 visit, you can see it says "mental status changes and  
22 weakness." And so, you know, you have to then figure out,  
23 you know, why it is that she's weak. She has a rapid heart  
24 rate which is -- can contribute to, to dizziness and  
25 weakness.

1 But the other thing they noticed during that  
2 hospitalization again is that she's had dark stools. And,  
3 so, bleeding can also contribute to dizziness and weakness.

4 Q. And let's go to 9007-A-25 and 26. I think this is what  
5 you may have been referring to. This is during that same  
6 time frame in mid-November of 2008; is that right?

7 A. That is correct.

8 Q. And the consultant here is Dr. Matthew Rohrbach who the  
9 jury's heard is a gastroenterologist locally here, maybe  
10 even a politician I think. Are you familiar with this being  
11 a gastroenterologist note?

12 A. I am.

13 Q. Okay. And what was significant about this particular  
14 note?

15 A. What is significant is, first of all, a  
16 gastroenterologist was consulted. So that would mean that  
17 whoever consulted the gastroenterologist was thinking that  
18 she's potentially bleeding.

19 Second, what he clearly noted is that her blood counts  
20 went down. So her hemoglobin went from 10 the day before to  
21 9. Hemoglobin of one point drop is a bag of blood, or a  
22 pint of blood. So it's not insignificant.

23 And then she -- he noted that she had darker than usual  
24 stools. And, again, as we talked about, dark black, that  
25 usually will indicate if you pair that up with a decreasing

1 hemoglobin in patient symptoms would indicate GI bleeding.

2 Q. And if we go to -- and then the note also indicated  
3 that she had been transfused two units as well. Is that  
4 significant?

5 A. That is correct. Again, they feel like her blood  
6 counts are too low. She has symptoms from them and they're  
7 dropping. So they felt like she was bleeding and they've  
8 given her blood.

9 Q. Okay. And if we go to the next page, 9007-26 on  
10 "Impression," it does indicate -- there's a reference to  
11 anemia and then talking about the possibility for a  
12 colonoscopy. What's the significance of this piece?

13 A. So, obviously, the gastroenterologist agrees that there  
14 probably -- there is blood loss. And, so, what the  
15 gastroenterologist is saying that he's going to work her up  
16 with an upper endoscopy, like we talked about before, and  
17 potentially a colonoscopy.

18 And he says, "We will start her work-up with the upper  
19 endoscopy," which is very reasonable. Usually we kind of  
20 will do the upper endoscopy first. It's easier. It doesn't  
21 take a prep. If you find a reason, then you can stop there.

22 And especially with her, Ms. Knight did have a lot of  
23 medical issues at that time as well. So that's sort of the  
24 easier procedure. And then if that's okay, at some point he  
25 was considering the colonoscopy.

1 Q. Okay. And from your review of the records, was a  
2 colonoscopy ever done on Mrs. Knight at this time frame in  
3 2008?

4 A. It was not.

5 Q. Okay. And do you know whether or not any further  
6 evidence of bleeding took place one way or the other after  
7 this particular time frame?

8 A. Not in November.

9 Q. All right. I'm finished with that exhibit.

10 MR. LEWIS: Judge, I wasn't sure when and if you  
11 were going to take a morning break today.

12 THE COURT: Well, let's go a little bit longer.

13 MR. LEWIS: Okay, fair enough.

14 BY MR. LEWIS:

15 Q. Did you review records after November of 2008 that  
16 discussed whether or not Mrs. Knight had had a prior bleed  
17 event as part of your work in this case?

18 A. Yes.

19 Q. Okay. And what's the significance of, of that? What's  
20 the significance of a medical record later in time that  
21 recounts a history of a patient prior to that?

22 A. It just notes that, you know, all the healthcare  
23 providers are in agreement that she's had a GI bleed.

24 Q. Let's take a look at Exhibit 9009-A, Page 273. This  
25 has been admitted. Here we have about a month, maybe even



1 just a couple of weeks later Dr. Gunnalaugsson -- do you  
2 understand that he's a treating cardiologist, Doctor?

3 A. I do.

4 Q. -- is commenting on his treatment of Mrs. Knight at  
5 this time. And if we look at the history of present  
6 illness, Dr. Gunnalaugsson says some things that you wanted  
7 to point out to the jury.

8 A. Yes. So he performed a stent of her heart. "So I did  
9 a stenting of her LAD," which is the major branch of the  
10 heart, "with a bare metal stent two weeks ago."

11 So one thing you'll notice is the reason they choose  
12 the type of stent for her is because of her, her history of,  
13 of bleeding. Bare metal stents require a shorter course of  
14 Plavix or an anti-platelet agent.

15 She has had some bleeding and, therefore, a bare metal  
16 stent was chosen.

17 Q. And then if we look at 9009-A-275 with the assessment  
18 or the plan -- I'll blow that up a little bit -- I wanted to  
19 reference again the middle of that paragraph. She's been on  
20 Coumadin, the next two sentences, and indicate whether  
21 that's significant to you from this treating cardiologist in  
22 December of 2008.

23 A. It is because he clearly acknowledges that she's had a  
24 bleed. So she -- and I'll quote him.

25 "She has been on Coumadin for atrial fibrillation but

1 this was stopped because of her chronic bleed."

2 Q. And is this also one of those situations where the  
3 doctor is considering triple therapy?

4 A. Absolutely.

5 Q. And how is this cardiologist feeling, at least from  
6 your review of the records, about whether Mrs. Knight could  
7 use warfarin as an anticoagulant on a triple therapy?

8 A. I mean, I think he's doing what, what he should be  
9 doing. He's, he's cautious. Right? He, on the one hand,  
10 wants to make sure her stent doesn't clot in her heart. He  
11 wants to make sure she doesn't get a stroke or a clot  
12 elsewhere. But at the same time, he wants to minimize her  
13 chances of bleeding.

14 So it's a struggle. It's not an easy situation. It's  
15 a, it's a difficult situation.

16 Q. And when we fast forward to February of 2009, at that  
17 point in time she's off --

18 And I'm finished with that. Thank you.

19 If we go to 9007, 9007-A-55 and 57, do we see the  
20 ramifications here?

21 And we'll just kind of orient ourselves with the date,  
22 February 8th of 2009. So this is, this is about two months  
23 after the note that we saw from Dr. Gunnalaugsson where she  
24 went off Coumadin. She had the bare metal stents placed and  
25 was on Plavix. And now something happens in February of

1 2009 on the other side.

2 A. Yes. So if you notice here, she did present with chest  
3 pain. But if you look here -- and is it okay if I mark  
4 this?

5 Q. Yes.

6 A. Okay. "The patient noticed that her fingertips," if  
7 you start there, "were turning discolored."

8 And what that indicates is that she had decreased blood  
9 flow to that arm. And what they subsequently discovered was  
10 it was due to a clot which, again, is the whole struggle  
11 here with -- unfortunately with Ms. Knight is, you know, the  
12 weighing the risks of bleeding and clotting. Again, it's a  
13 very complicated situation.

14 Q. Okay. And if we go to 9007-A-57, we see under  
15 "Assessment" acute right brachial emboli. What is that,  
16 Doctor? Do you know what that is?

17 A. Yeah. So the brachial artery is the major artery in  
18 the arm. And presumably what's happened is because she has  
19 atrial fibrillation, your blood flow in your heart is not  
20 normal.

21 And, so, there are areas of the heart that don't move  
22 as well. And those are areas where blood can clot. And  
23 when blood clots in the heart, it will, it will flick off  
24 and it can go to other places in the body.

25 Obviously, the most severe area is the brain. But

1 sometimes it can go to other areas such as the extremities,  
2 the arms, the legs. It can essentially go anywhere in the  
3 body.

4 Q. And then if we look at number four, we see sort of what  
5 I think you've already indicated, but she wasn't on Coumadin  
6 at this time because she had had a stent procedure where  
7 Plavix was used to prevent clotting in the stent.

8 A. That is correct.

9 Q. Okay. And the plan here, even though she had had a  
10 clot or an emboli, was not to put her on Coumadin at this  
11 time; right?

12 A. That's correct.

13 Q. Okay. Are you aware -- but they wanted to continue  
14 Plavix; is that right?

15 A. Yes.

16 Q. Okay. They just don't want to, again, combine the  
17 three all at once. Is that what appears to be the case?

18 A. That is correct.

19 Q. Okay. Are you aware that she eventually did start back  
20 on Coumadin at some point in time in 2009?

21 A. She did.

22 Q. Okay. And if we look at 9005-A, Pages 26 and 27, that  
23 takes us to March of 2009. And we see here a note, again  
24 just to orient everyone, from Dr. Gunnalaugsson, her  
25 cardiologist, and he's talking about what his, I guess,

1 observations are of her at this point in time. What's  
2 significant about the kind of history that he's recounting  
3 here?

4 A. So he states specifically that she had not been on  
5 Coumadin because of her GI bleed. So that's -- and then  
6 he's also noting that she had an embolus down her right arm.

7 Q. Is that the record we just looked at, the fingertips?

8 A. Yes. That was the hospitalization we looked at. And  
9 then she was since put on Coumadin which would, again, make  
10 sense to put somebody who's having clots on a blood thinner.

11 Q. Okay. And if we look at 9005-A, Page 27, under  
12 "Assessment and Plan," there's some information here as well  
13 that you wanted to point out to the jury. Is that right?

14 A. Yeah. So on the second sentence it says, "The patient  
15 has a serious problem with anemia requiring blood  
16 transfusions. Unfortunately I don't think she can take  
17 Coumadin, aspirin and Plavix."

18 So at that point they stopped the Plavix now and that's  
19 because she's been on the Plavix for over a month since her  
20 stent. So -- and, again, we can see that the physician is  
21 struggling. "There may be a slight increase of stent  
22 thrombosis because ideally you would be on Plavix for  
23 greater than a month. But I think the risk of her having a  
24 bleed at this point outweighs that risk."

25 Q. So -- thank you for that. So, Dr. Shami, based on the

1 records that you've seen and the physicians that you've seen  
2 their records and you've looked at their testimony, what do  
3 you think, in your opinion, is occurring in the 2009 time  
4 frame with respect to Mrs. Knight's warfarin experience?

5 A. I think it's challenging. I think -- you know, first  
6 of all, like we talked about, the levels were difficult to  
7 control.

8 Second of all, you know, she was having some bleeding  
9 from 2008. And then she comes off of the warfarin and she  
10 gets an arm clot.

11 So it's a -- again, it's a very, it's been very  
12 challenging for the physicians and for Ms. Knight.

13 Q. Okay. And the jury has heard that Pradaxa came to the  
14 market in 2010. So in this time frame are you aware of any  
15 other anticoagulant medication that was available to help  
16 with patients who were struggling on warfarin?

17 A. No.

18 Q. Okay. That only came later with Pradaxa and some of  
19 the others such as Xarelto and Eliquis that the jury's heard  
20 about?

21 A. That is correct.

22 Q. As part of your work in this case did you take a look  
23 at sort of the, the medications that Mrs. Knight happened to  
24 be taking along with the dosage adjustments that were  
25 required in combination with the INR readings that her

1 physicians had made?

2 A. I did.

3 Q. Okay. And we have a demonstrative. Let me just ask  
4 you generally.

5 A. Okay.

6 Q. I should just pull up the demonstrative. This would be  
7 the dose adjustments in July of 2009.

8 A lot going on in this demonstrative. And, again, this  
9 is something that I prepared with the trial graphics folks  
10 that we have. But it is a reflection of medical records  
11 that you have reviewed in this case. Is that fair to say,  
12 Dr. Shami?

13 A. That is fair to say.

14 Q. Okay. And what, what are we trying to kind of display  
15 here in this time frame?

16 A. So what you notice is, you know, this is the dosage  
17 here in milligrams of warfarin that has been prescribed.  
18 And if you go from week to week, you notice that the amount  
19 of warfarin needed has changed.

20 And the reason for that is initially you see this INR  
21 of 1.6. Again, you want to be in the range of 2 to 3. So  
22 then they go up to 7 milligrams, right, and then they check  
23 another INR. So they go to 6 milligrams. They recheck that  
24 INR the next day and still go up.

25 So you can see it's been very challenging and they,

1 they -- understandably her physicians -- I presume this is  
2 Dr. MacFarland -- continue her on the higher dose of  
3 warfarin.

4 And then on the 15th what you notice is that INR is 8.  
5 So it's well above the range of 2 to 3. And that can be  
6 dangerous.

7 So what they've done is they actually sent her to the,  
8 I believe to the hospital for a Vitamin K shot to try to  
9 decrease that. And then they hold this. They hold the  
10 warfarin here. They hold it here. And they hold it here.

11 And then again her INR comes back .8 which is too low.  
12 And then they have to go back up on that warfarin.

13 Q. Okay. And this is just, just kind of a demonstrative  
14 month in Mrs. Knight's history that we picked out.

15 Based on your review of the records, is this consistent  
16 with what life was like for Mrs. Knight while on warfarin?

17 A. That is correct.

18 Q. Okay. Just so I make sure that I understand what this  
19 is showing is that on July 7th and 8th Mrs. Knight's INR  
20 readings are under the therapeutic range. And does that  
21 mean she is at a higher stroke risk?

22 A. Yes, she's at a higher stroke risk when the INR is less  
23 than 2.

24 Q. Okay. So they up the warfarin dosage to make her blood  
25 thinner and avoid the stroke risk. Is that what's going on



1 there?

2 A. That is correct.

3 Q. And then by July 15th her blood is becoming too thin.

4 And is that what those INR readings of 8 are showing?

5 A. Yeah. So here it's very, very thin. Again, it's way

6 above 3. And that's where they were concerned

7 appropriately. And she received the Vitamin K shot on the

8 16th.

9 Q. Okay. And with the INR readings of 8, that's -- in

10 your view is that a significant bleed risk for a patient

11 that has an INR of 8?

12 A. Sure. It's high. It's not ideal.

13 Q. Okay. And then after the Vitamin K shot and holding

14 the Coumadin, her INR levels are tested. And now she's back

15 down with a higher stroke risk because it's under 2. Is

16 that what that's showing?

17 A. That is correct.

18 Q. Okay. So in the span -- let me make sure that I

19 understand. So in the span of a month she was at a higher

20 stroke risk on two different occasions and at a significant

21 risk of bleed on another occasion that month for her?

22 A. That is correct.

23 Q. Okay.

24 MR. LEWIS: I'm finished with that. Thank you.

25 BY MR. LEWIS:

1 Q. Now, do you recall, Doctor, that by October of 2011  
2 Mrs. Knight's experience on warfarin led to a change in her  
3 treatment for anticoagulant medication?

4 A. Yes, that is correct.

5 Q. Okay. And what happened in October of 2011 based on  
6 your review of the medical records and the testimony?

7 A. Yeah. I think if you look at the records and look at  
8 specifically Dr. MacFarland's notes, it was felt that  
9 Coumadin was no longer the appropriate anticoagulant and  
10 that there was a need for another one and it shows Pradaxa.

11 THE COURT: Would this be a good point to --  
12 Would you folks like a little break?

13 All right. We're going to take about a ten-minute  
14 recess. As a result, we'll probably go past noon before we  
15 take a break.

16 You can step down. Don't discuss your testimony.

17 You may retire to the jury room. Remember my previous  
18 instructions.

19 We'll take a ten-minute recess.

20 MR. LEWIS: Thank you, Your Honor.

21 (Recess taken at 11:23 a.m.)  
22  
23  
24  
25

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1 (Back on the record at 11:36 a.m.)

2 THE COURT: All right. Ready to go? Bring the jury  
3 out.

4 (Jury present.)

5 THE COURT: All right. Be seated.

6 Mr. Lewis, you may resume.

7 MR. LEWIS: Thank you, Your Honor, members of the  
8 jury.

9 Dr. Shami, we were talking about the time frame of  
10 October 2011 right before the break and, in particular, the  
11 switch that occurred in Ms. Knight's anticoagulant treatment  
12 at that time.

13 Q. Do you recall our discussion there?

14 A. I do.

15 Q. Okay. And in particular, the reason for that switch, from  
16 your understanding of the medical records and the testimony  
17 that you read, was what?

18 A. Ah, was the fact that it was so difficult to manage her on  
19 warfarin. And she was at such a high risk of stroke and  
20 emboli, which we just showed that she had in November prior to  
21 that, that it was a struggle. And she needed to be on an  
22 anticoagulant, but the warfarin just did not work for her.

23 Q. Okay. And is there support from Mrs. Knight's own  
24 physician on that point?

25 A. There is.

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1 MR. LEWIS: If we could look at 9009A, page 580 and  
2 581 -- we'll go to 580 first, if we may.

3 Q. Okay. So, Doctor, tell us what this document reflects and  
4 if you're familiar with something like this.

5 A. I am. This is a prior -- this is an authorization form.

6 So oftentimes insurance companies want you to justify or  
7 give a reason for a drug switch, so why is it that you're  
8 going from one drug or, i.e., one anticoagulant to another  
9 anticoagulant. So oftentimes we're required to fill these  
10 forms out.

11 And if you look at this form, the prescriber name is Dawn  
12 MacFarland, Ms. Knight's primary care physician. And the  
13 diagnosis, which would be the reason why you're doing this  
14 switch, is sporadic -- which means intermittent, on and off --  
15 and supratherapeutic, which means above the 2 to 3 INR range,  
16 on coumadin. So that's the reason why she was switched.

17 Q. And if we look at the addendum, which was the next page,  
18 9009A-581, does Dr. MacFarland provide a time frame for which  
19 this has been occurring for Mrs. Knight?

20 A. Yes. She says since 2008 until present.

21 Q. Based on your review of the records, the medical records  
22 that you've seen -- and we've covered many of them this  
23 morning -- do you agree with Dr. MacFarland's statement right  
24 here?

25 A. I do.

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1 Q. Do you agree that a switch from warfarin or coumadin was  
2 warranted at this time?

3 A. Yes. She needed to be on an anticoagulant, and she --  
4 obviously this wasn't the drug.

5 Q. Now, you read Dr. Ashhab's testimony, and we're going to  
6 talk about the May 2013 bleed event that occurred in just a  
7 few minutes. But Dr. Ashhab says, you know what, if she just  
8 would have stayed on warfarin, she would not have had that  
9 bleed event.

10 Do you agree with that?

11 A. No.

12 Q. Why not?

13 A. I mean, how could you say, when somebody has had a history  
14 of GI bleeding -- we know what she bled from, an AVM. She  
15 could have bled whether she was on no medications, whether she  
16 was on warfarin, whether she was on Pradaxa. And keep in  
17 mind, she was also on aspirin and Plavix. So the ability to  
18 state that she absolutely would not have bled if she was on  
19 warfarin doesn't make sense to me.

20 MR. LEWIS: Thank you. Finished with that.

21 The second thing I asked you to do was to look into  
22 Mrs. Knight's experience with Pradaxa.

23 Q. And you know that she went on Pradaxa in roughly October  
24 of 2011 right after this change was made consistent with Dr.  
25 MacFarland's note, correct?

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1 A. That is correct.

2 Q. And did you look at the medical records for -- and let's  
3 just reference point the 18 or so months prior to the April of  
4 2013 stent procedure that the jury has heard about that Mrs.  
5 Knight underwent.

6 Did you look at the medical records to see if Mrs. Knight  
7 was having any problems on Pradaxa?

8 A. No. For those 18 months, from what I could gather from  
9 all of the records -- and those 18 months are very complete --  
10 that she had had no problems with taking the Pradaxa drug.

11 MR. LEWIS: Okay. And if we could just look at the  
12 eighteen -- the demonstrative. I'm sorry. That was a  
13 terrible description of that.

14 Q. This is the time frame, is it not, Dr. Shami, for which  
15 you've looked at the medical records and discovered no stroke  
16 and no bleed or other problems while -- that were linked to  
17 Pradaxa?

18 A. That is correct.

19 Q. Okay. Now I want to draw up on this board, I'll just kind  
20 of draw one line here.

21 Did you look at the medications that Mrs. Knight was on  
22 during this time frame to determine, for instance, if she was  
23 on other medications like P-gp inhibitors?

24 A. Yes, I did. So P-gp inhibitors are permeability  
25 glycoproteins, which I think you have probably heard about by

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1 now. But they're little proteins that are on the cell  
2 membrane, and they transport things outside of the membrane --

3 Q. Okay.

4 A. -- just to begin with.

5 Q. Okay. And was Mrs. Knight on P-gp inhibitors prior to the  
6 April 2013 stent procedure while she was on Pradaxa?

7 A. Yes.

8 Q. Okay. To the best of your recollection, was Mrs. Knight  
9 on at least sporadically or intermittently aspirin during that  
10 time?

11 A. She was on aspirin.

12 Q. We know she was on Pradaxa --

13 A. Correct.

14 Q. -- for that 18 months.

15 Was Mrs. Knight at that point in time over the age of 75?

16 A. Yes, she was. She was 83.

17 Q. She was not on Plavix, correct?

18 A. Not before April of 2013, she was -- that's correct.

19 Q. Not on Plavix.

20 So between the time that she began taking Pradaxa in  
21 October of 2011 and April of 2013, there were no Plavix  
22 prescriptions for Mrs. Knight; is that correct?

23 A. That is correct. And she did well on the Pradaxa during  
24 that period of time.

25 Q. Now, are you -- you're familiar with the medication

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1 Pradaxa obviously with patients that come to see you?

2 A. That's another medication that's been out there not as  
3 long as warfarin, but -- but for years.

4 Q. All right. And as part of your work in this case, did you  
5 review the physician label and product information that came  
6 with the Pradaxa medication?

7 A. Yes.

8 Q. Okay. And did you assess whether the product information  
9 and the label were a reasonable and appropriate description of  
10 the risks and benefits associated with the medicine?

11 A. Absolutely.

12 MR. LEWIS: If we could take a look at 5889. It's  
13 been admitted into evidence.

14 We see here that --

15 Q. And by the way, have you reviewed the different labels --  
16 you see here in the upper left that Pradaxa was initially  
17 approved in 2010. There were different labels over time. As  
18 information became available, the labels changed.

19 Is that fair to say?

20 A. Absolutely. And we, as physicians, will periodically  
21 re-review labels on the medications our patients are on.

22 Q. Okay. And when you do that, do you ever look on this  
23 left-hand side where it says Recent Major Changes?

24 A. I do.

25 Q. Okay. Why would you do that as a physician?



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1 A. Well, I mean, you want to know whether there have been any  
2 new warnings just for the safety of your patient. Ah, it  
3 would behoove me, and as well as my patient, to know that.

4 Q. Okay. Now if we scroll down a little bit further, in the  
5 bottom right we see that this is the label from April of 2013  
6 that I wanted to discuss with you.

7 A. That is correct. That is -- at the time, this is the  
8 label that was available at that time of the -- of the  
9 stenting procedure --

10 Q. Right.

11 A. -- and prior to her bleeding.

12 Q. Okay. So some of the other labels before this may have  
13 not had the information that this particular label had in it.  
14 Fair to say?

15 A. That is correct.

16 Q. And some of the earlier labels, like the very first label  
17 in 2010 in particular, did not have under Warnings and  
18 Precautions -- or excuse me -- under Drug Interactions: P-gp  
19 inhibitors in patients with severe renal impairment, Pradaxa  
20 use not recommended.

21 That wasn't in the original label --

22 A. You are correct.

23 Q. Okay. It got --

24 A. That was not.

25 Q. It got updated in 2012 or something along those lines?

1 A. January 2012, I believe.

2 Q. Okay. But when the physicians who went to prescribe  
3 Pradaxa for Mrs. Knight in April of 2013, that was in the  
4 label.

5 Is that your understanding?

6 A. This was -- this was the label, yes, that is correct.

7 Q. All right. Now, were the doctors who were treating and  
8 prescribing Pradaxa in April of 2013 different than the  
9 original physician who prescribed Pradaxa for Mrs. Knight in  
10 2011?

11 A. So it looks like Dawn MacFarland, from my understanding of  
12 the records, so looking at it, had prescribed the first  
13 prescription. She did have other providers prescribe, you  
14 know, Pradaxa at times, but it was mostly Dawn MacFarland.

15 So one of two things. If a new provider is writing a  
16 prescription, they will usually look again, re-review to make  
17 sure there is no difference in the label.

18 The other thing is, you know, I'm sure Dr. MacFarland, as  
19 any conscientious physician would, would intermittently -- I'm  
20 not saying every time, but intermittently review to make sure  
21 there are no updates on labels.

22 Q. Okay. And by April of 2013, Dr. MacFarland is out of the  
23 picture, and there are some new physicians --

24 A. There is. Abdelgaber, I believe, is her new primary at  
25 that time.

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1 Q. Okay. All right. Let's get back to the label.

2 So have you looked at the Medication Guide that also  
3 accompanies the physician label? Did you look at all the  
4 product information --

5 A. I did.

6 Q. Okay. And why don't you tell the jury about your views on  
7 whether the risks associated with the use of Pradaxa, as a  
8 practicing clinician, someone who treats folks who come in  
9 with bleed events, whether the information contained in the  
10 physician label and the Medication Guide are reasonable  
11 disclosures of risks.

12 A. I do think they're reasonable.

13 Q. Okay. And at a high level, could you explain why?

14 A. So which one, the label or the Medication Guide?

15 Q. Let's take them one at a time. Let's talk about the  
16 physician label to begin with.

17 A. Sure.

18 So if you look at the physician label, there is clear, you  
19 know, warnings of the expected bleeding risks. So obviously  
20 you're on anticoagulation, so your chances of bleeding are  
21 higher.

22 With the test of time, they've had more and more data  
23 since -- again, this was approved in 2010. Now this label is,  
24 you know, 2013. People have realized, okay, there are certain  
25 risk factors again that increase your chances of bleeding,

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1 those being the G-pg inhibitors, age, creatinine clearance or  
2 renal problems. And so all of this is clearly defined in this  
3 label.

4 In terms of the Medication Guide, and I don't have it in  
5 front of me, but I can tell you that patients want to know  
6 globally -- I would as a patient want to know, you know, what  
7 am I at risk of? And it clearly says bleeding on there.

8 And then it says that please, you know, tell your doctors  
9 if you're on other medications. It actually asks the  
10 physician -- there's a statement there, please inform them of  
11 all of the medications you're taking.

12 And it also goes on to say, you know what, if you want  
13 more information, you can request the physician --

14 Q. So if we look --

15 A. -- label.

16 Q. I'm sorry. I didn't meant to interrupt.

17 If we look at Exhibit 5889, page 12, we see towards the  
18 back of that exhibit the actual Medication Guide sort of  
19 attached to the back. So both are in that same exhibit.

20 And that's the Medication Guide that you reviewed as part  
21 of your work in this case?

22 A. That is correct.

23 Q. And if -- I'm sorry. Go ahead.

24 A. No. I mean, what I was saying is clearly it identifies  
25 you may have a higher risk of bleeding if you take Pradaxa and

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1 are over 75 years old, have kidney problems, have stomach or  
2 intestinal bleeding. I mean, they identify risk factors for  
3 increased bleeding, which I as a patient would want to know.

4 Q. Okay. There's also a mention of taking other medications.

5 And is there a specific call-out for Plavix?

6 A. No.

7 Q. On the Medication Guide, if we look at the fifth bullet  
8 point on that -- on the specific Medication Guide page, not  
9 the physician label.

10 A. I'm sorry. So what page are we on?

11 Q. On 5889-12.

12 A. Oh, yeah. I see what you're asking. I'm sorry. I  
13 misunderstood your question.

14 So is there a specifically -- does it specifically state?  
15 Yeah, it specifically states a handful of medications, and I  
16 can -- wait, let me see what they are.

17 Plavix is one of them. It says here coumadin, heparin,  
18 Plavix, Effient. So it states those in particular, but that's  
19 not all inclusive. I mean, there are other ones, and that's  
20 why they suggest telling your physician what medications  
21 you're on.

22 Q. Right. And so let's go to that, 5889-14 in bold, about  
23 the third paragraph down.

24 Was that what you were referring to with respect to  
25 telling the doctor?

1 A. That is correct.

2 Q. Okay. So I want to ask you about this just for a second,  
3 about the communication.

4 Do you prescribe medications -- maybe not Pradaxa, but do  
5 you prescribe medications for some of your patients?

6 A. Yes, I do. Not Pradaxa, but other medications --

7 Q. Okay.

8 A. -- that's true.

9 Q. And when you do, what is your normal process for talking  
10 with a patient about a medication that you're going to  
11 prescribe?

12 A. So the majority of the time -- so if it's in clinic or if  
13 it's after a procedure -- if it's after a procedure, I'll  
14 bring a family member in because usually the patient has been  
15 sedated. And what I'll do is I'll say, you know, this is what  
16 you need. Usually it's going to be an acid suppression  
17 medication, such as omeprazole or pantoprazole, because we use  
18 that very, very commonly in gastroenterology.

19 And what I'll do is I will sit down and say, listen, this  
20 is why I think you should take it, this is the reason for the  
21 dose, and these are potential side effects. And it's not like  
22 a one-way decision. It's a mutual decision that we make  
23 together.

24 It's rare that a patient or a family says, no, you know,  
25 we don't want to be on that medication if it's recommended by

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1 the physician. But, I mean, it does happen for -- for, you  
2 know, reasons. And so I think it's -- again, it's very  
3 important to sit down and review all of that, and that's  
4 standard -- pretty standard care.

5 Q. Okay. Have you ever, when prescribing a medication, just  
6 handed a patient a document and let them make the decision for  
7 themselves?

8 A. Absolutely not.

9 Q. Okay. Have you always had a verbal conversation where you  
10 talk with the patient about the risks and benefits of the  
11 medication?

12 A. I do.

13 I have had instances where I don't feel strongly -- it's  
14 rare -- either way, and then I will -- you know, again, I may  
15 not indicate 100 percent. But, yeah, absolutely will not just  
16 give a document over. That's not practicing good medicine.

17 Q. And do you think it's reasonable for a maker of medicine  
18 like Boehringer to, in the document that is supposed to go to  
19 the patient, encourage a discussion between doctor and  
20 patient?

21 Do you --

22 A. Yes.

23 Q. -- think that is a reasonable thing to do?

24 A. Yes.

25 Q. And if we go to the next page, 5889-15, general

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1 information about Pradaxa, I think this is the other piece of  
2 this Medication Guide that you were referring to.

3 But in the middle paragraph, it says: This Medication  
4 Guide summarizes the most important information about Pradaxa.  
5 If you would like more information, talk with your doctor.  
6 And you can ask either the pharmacist or the doctor for more  
7 information, such as the physician label, the health  
8 professional document.

9 So let me ask you this. Have you had patients, in the  
10 course of your clinical practice, ask for that information?

11 A. Yes.

12 Q. Have you provided it to them?

13 A. Yes.

14 Q. Do you think it's a reasonable thing for a maker of  
15 medicine like Boehringer to do, to make the physician label or  
16 to suggest that the physician label is available to patients  
17 who want to consider that information?

18 A. I do.

19 Q. So to wrap up your opinions with respect to the Pradaxa  
20 physician label and product information that we're looking at,  
21 is it your opinion to a reasonable degree of medical and  
22 scientific certainty that the product information and the  
23 physician label are adequate disclosures of risks to patients  
24 and doctors?

25 A. Yes.



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1 Q. And do you hold that opinion to a reasonable degree of  
2 medical and scientific certainty?

3 A. I do.

4 MR. LEWIS: I'm finished with that. Thank you.

5 Now I want to go to the next opinion, the next thing I  
6 asked you to do, and that was to discuss what caused or the  
7 source of Mrs. Knight's GI bleed in May of 2013.

8 Q. Describe for me a little bit about what was going on with  
9 Mrs. Knight's care, from your review of the records, around  
10 the time of April and May of 2013.

11 A. So in April, that was when she had two heart stents  
12 placed. And anytime you have a stent, you have to decide --  
13 again, the cardiologists have an option of stents, and they  
14 chose again a bare metal stent like they had in the past. And  
15 that was -- you can see in the notes, they were again  
16 struggling because she needed to be on Plavix. And with her  
17 history of chronic bleeding, it's a difficult decision but, on  
18 the other hand, you don't want her to have a heart attack.

19 So they started her on triple therapy. So she was -- at  
20 that point in April, when she was discharged, she was on  
21 aspirin, Plavix and Pradaxa.

22 Q. And let's look at that record just to be clear. That  
23 would be 9007A, page 94.

24 We see here this is roughly the time frame, April 22nd,  
25 2013, and there is a description of the procedures.

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1 Are the doctors here describing the procedure, the stent  
2 procedure that you just talked about?

3 A. Yes. So they're describing placement of two stents, and  
4 it's, I think, Dr. Maru. I hope I'm saying his name  
5 correctly. He was substituting because her primary -- it  
6 sounds like cardiologist was out of town.

7 Q. Okay. And Dr. Graham was also involved in some way at the  
8 hospital?

9 A. That is correct.

10 Q. Okay. And if we go to page 9007A-95, towards the bottom  
11 there is a recommendation.

12 A. Yeah.

13 They say: Continue aspirin indefinitely and Plavix for a  
14 minimum of four weeks, preferably longer if the patient can  
15 tolerate.

16 So ideally, again, even with bare metal stents -- and I'm  
17 not a cardiologist, but I do know -- I've had many patients  
18 with cardiac stents, they would ideally be on Plavix for three  
19 to six months. So the longer you are on Plavix, the better in  
20 terms of putting a clot or a stent thrombosis, we call it.

21 The first month of the bare metal stent is kind of the  
22 critical month. But if patients can tolerate being on it  
23 longer, that's ideal.

24 Q. And then it goes on to say: Her Pradaxa will be resumed  
25 tonight. And due to triple therapy -- we kind of have a mid

1 sentence here.

2 Due to triple therapy, and it goes onto the next page to  
3 say --

4 A. I am not sure the patient will tolerate long-term Plavix,  
5 so minimum would be four weeks, and that's the main reason  
6 bare metal stenting was chosen during this PCI procedure, just  
7 a percutaneous catheterization.

8 Q. Okay. And so what is this telling you about the decision  
9 that the doctors are making and the balancing of risks and  
10 benefits that the doctors for Mrs. Knight are making at this  
11 time that she has the stent procedure?

12 A. Again, it's a very difficult situation between, you know,  
13 clotting and bleeding. It's a very, very challenging  
14 situation, one that we as gastroenterologists and  
15 cardiologists have to discuss all the time. Ah, we have to  
16 weigh the risks and benefits of any treatment that we do.

17 Q. Now, eventually she has, Mrs. Knight has a GI bleed in May  
18 of 2013.

19 A. Yes, she does.

20 Q. I'm going to talk about that in a second.

21 But are you familiar with the medications and the  
22 circumstances of Mrs. Knight between the time she had the  
23 stent procedure and May of 2013?

24 A. Yes. So in April when she was discharged, she was  
25 discharged on all of her prior medications, and one was added

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1 on. And that was Plavix was added on to her regimen.

2 Q. So --

3 A. So --

4 Q. -- at that point -- we just saw aspirin.

5 So she was still on P-gp inhibitors?

6 A. She was on P-gp inhibitors.

7 Q. Pradaxa was started, and obviously Mrs. Knight at the time  
8 was over 75.

9 And then at this point in time, Plavix is added to her  
10 therapy; is that right?

11 A. Yes, Plavix is added to her therapy.

12 Q. Okay. And during this time that Plavix was added, she had  
13 a GI bleed; is that right?

14 A. Yes. In the context of triple therapy, that is correct.

15 Q. Okay. Let's talk about the GI bleed for a second.

16 Have you reviewed the records associated with Mrs.  
17 Knight's GI bleed from May of 2013?

18 A. Yes.

19 Q. Okay. And the jury's already heard from the  
20 gastroenterologist who performed the procedure to stop the  
21 bleeding, Dr. Huh.

22 Have you reviewed his description of what he did and the  
23 records associated with that?

24 A. I did.

25 Q. Okay. We're going to look at a couple of the records, but

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1 just at a high level, Doctor, what is your view on how the GI  
2 bleed that Mrs. Knight had in May of 2013 was treated?

3 A. So -- yeah.

4 So looking at Dr. Huh's -- his consult notes, she was  
5 initially seen by her primary care physician in the clinic and  
6 then admitted to the hospital, and they consulted GI.

7 Dr. Huh noticed that she had had six days or -- you know,  
8 or so of bleeding. Fortunately Mrs. Knight was very stable.  
9 Her heart rate was normal, her blood pressure was fine, and so  
10 they had chosen to put her on the floor.

11 Dr. Huh saw her in consult and noted she was bleeding,  
12 also noted she was stable, and made a very reasonable decision  
13 to proceed with watching her and having her prep overnight to  
14 do the colonoscopy and upper endoscopy. The AVM was found and  
15 was promptly treated the next day.

16 Q. So let's walk through a couple of the medical records that  
17 were associated with that particular event. We'll start with  
18 9003A-386 to 389.

19 And you see that at this time, this is May of -- May 20th  
20 of 2013?

21 A. I'm sorry. Mr. Lewis, I think I -- you said nine zero  
22 zero --

23 Q. I'm sorry. 9003-386. And this is the one where the  
24 labels are really small at the bottom. I apologize.

25 A. Got it.

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1 Q. Okay. And this is Dr. Abdelgaber's record when Mrs.  
2 Knight initially presented on May 20th, 2013; is that right?

3 A. That is correct.

4 Q. Okay. And what does he note as far as the history and the  
5 chief complaint?

6 A. So the chief complaint is dizziness and blood in stools,  
7 so she's clearly having a GI bleed. And he says the blood was  
8 initially mixed with the stools, then it started coming on top  
9 of the stools. And then just blood with lots of blood clots  
10 is what he states.

11 Q. And how long had it been -- based on his record, how long  
12 had there been some suggestion --

13 A. It had been going on for days.

14 Q. And Dr. Abdelgaber did a physical exam.

15 That would be appropriate in the instance, I would assume?

16 A. Absolutely.

17 And if you look at the physical exam notes, and I was kind  
18 of alluding to that before, fortunately Mrs. Knight was  
19 sitting comfortably, and she was in no apparent distress. If  
20 somebody is having a really, really brisk GI bleed, they don't  
21 feel comfortable. They are in distress. They are short of  
22 breath, having chest pain. You know, something is usually  
23 going on. Their blood pressure is really low. Patients can  
24 pass out. But fortunately Mrs. Knight was stable.

25 Q. Okay. And have you had patients that have had bleed

1 events where they presented to you, and this wasn't the  
2 situation, it was a different situation, a more serious  
3 situation?

4 A. Almost every day.

5 Q. And if you were taking a doctor note in that kind of a  
6 situation, what would you say if the patient had a very, very  
7 serious, severe, distressful bleed event?

8 A. You mean unlike --

9 Q. Yeah.

10 A. -- Mrs. Knight?

11 I would -- well, I mean, I would automatically call the  
12 intensive care unit and transfer them right to the intensive  
13 care unit.

14 Q. Okay. And did that happen with Mrs. Knight?

15 A. No. My understanding from the records is she was on the  
16 floor. She was sitting comfortably, and her vital signs were  
17 stable. There was no reason for the intensive care unit.

18 Q. Okay. and if we look at the next page, 9003A, again under  
19 Neurological, is that important information, alert and --

20 A. Yeah.

21 Like I said, if you have brisk bleeding, and your blood  
22 counts drop extremely quick -- so not only does it have to do  
23 with the quantity of blood, but what we say the acuity, how  
24 fast it drops. So if you drop it all in one day, that is  
25 different than if you drop it over five or six days, because

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1 your body can get -- can adjust for it over a period of time.

2 So she is alert, fortunately she's awake. And moving all  
3 extremities means, you know, she is healthy, and she's doing  
4 well.

5 Q. Okay. And if we --

6 A. I don't know about healthy, but she's definitely doing  
7 well.

8 Q. And if we look at the plan at the bottom, Dr. Abdelgaber  
9 suggests that she's going to need further workup and to get a  
10 gastroenterologist involved.

11 A. Absolutely.

12 Q. And that's the --

13 A. And that's the right thing --

14 Q. That's the right thing to do?

15 A. The right thing to do.

16 Q. Okay. Now all bleeds are serious, though?

17 A. Absolutely.

18 Q. And this was a bleed that needed to be treated by a  
19 gastroenterologist.

20 A. Absolutely.

21 Q. I don't want to minimize --

22 A. No.

23 Q. -- this situation.

24 But on the scale of things, it was a good thing that she  
25 was stable, her vital signs were fine, and she was able to not



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1 have to go into ICU or an emergency situation.

2 Is that fair?

3 A. Absolutely.

4 Q. The next record will be 9007A, page 107.

5 I think this was also -- so now we're looking at Dr. Huh,  
6 and this is also on the same day.

7 So Dr. Huh is the gastroenterologist; is that right?

8 A. He is.

9 Q. And so he gets the referral from Dr. Abdelgaber on that  
10 same day, and he does an assessment.

11 Is that fair?

12 A. He does assess Mrs. Knight, correct.

13 Q. And that's what you want to do as a gastroenterologist, is  
14 assess the situation to see whether immediate action needed to  
15 take place or some other plan could be put in place.

16 Is that fair?

17 A. That is correct.

18 If she was having an extremely severe bleed and was in the  
19 ICU and losing blood, my decision as a gastroenterologist, and  
20 I'm sure as Dr. Huh would do, would be to admit or transfer  
21 the patient to the intensive care unit and do that colonoscopy  
22 and upper endoscopy immediately.

23 What we can do is -- the upper endoscopy is easy enough.  
24 The colonoscopy sometimes, if we need to do it urgently, is we  
25 can put -- we can either ask the patient to drink real fast.

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1 And if they can't, we can put a tube into the stomach through  
2 the nose -- we do it quite a bit -- and then pour the prep in  
3 there and do what is called a rapid prep. But fortunately in  
4 Ms. Knight's case, that was not needed.

5 Q. Okay. If we go to 9007, page 108, the next page, Dr. Huh  
6 himself performs a review of the systems and a physical  
7 examination; is that right?

8 A. He does.

9 Q. Okay. Let's be fair, when we go to general, Mrs. Knight  
10 is reporting fatigue and weakness?

11 A. Absolutely she is.

12 Q. Okay. And is that something that is common with all GI  
13 bleeds?

14 A. Yeah, it is. It's not what you want, but it is -- it is  
15 common with GI bleeds.

16 Q. Okay. And if we look at the physical exam, is Dr. Huh  
17 finding sort of the same thing that Dr. Abdelgaber found with  
18 respect to whether she was stable or not?

19 A. Yes. He has assessed her and concluded that she was  
20 stable. He was obviously in agreement with keeping her on the  
21 floor and felt, looking at this note, that she was -- you  
22 know, she can have a prep overnight and that they can do the  
23 procedure the next day.

24 Q. Okay. And that's on page 9007A-109, which is the next  
25 page.

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1 A. That is correct.

2 Q. And if we look at Assessment and Plan --

3 A. It says, under 3: We will plan EGD and colonoscopy -- so  
4 an esophagogastroduodenoscopy is so long a word, that is why  
5 we use EGD -- and colonoscopy in the AM. Continue to hold  
6 aspirin and Plavix and Pradaxa for now. We will set coags --  
7 it sounds like they didn't get an INR or a PTT at the time --  
8 and we will change oral proton pump inhibitors to IV.

9 Q. Okay. And we also know that there was a note on blood  
10 loss above on the diagnostic data.

11 A. That is correct.

12 Q. Okay.

13 A. If you look at her hemoglobin, so that's the number we've  
14 been sort of talking about this entire morning, at baseline,  
15 her hemoglobin was 10. 11, 10, when she got down to 9 while  
16 she was in the hospital in November of '08, as you recall, she  
17 needed blood transfusions.

18 So here she is 6.4, so her drop is more significant than  
19 it was during her last GI bleed.

20 Q. And Dr. Huh took that into consideration when he decided  
21 to design the plan to have her stay overnight and handle the  
22 situation the next day?

23 A. Absolutely.

24 So what he did is he gave her two units -- or I don't know  
25 who physically gave her the two units of blood, but the

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1 physicians agreed that she needed two units of blood.

2 Q. Okay. And do you have any criticism at all of Dr. Huh, in  
3 the face of this diagnostic data, waiting overnight and  
4 handling the event the next morning?

5 A. Absolutely not. He did exactly what I would personally  
6 do.

7 Q. If we look at the next -- and by the way, did you review  
8 the records associated with the -- first of all, did Dr. Huh  
9 perform a surgery on Mrs. Knight?

10 A. No.

11 Q. Would you characterize -- how would you characterize --

12 A. Yeah, absolutely.

13 So we're not surgeons. Some -- we're gastroenterologists.  
14 We're proceduralists. So surgery is when you cut through the  
15 skin. We don't do that. The only time we ever do anything to  
16 the skin is a feeding tube. We are not -- we do not cut  
17 people open. We do not go from outside in. We work all  
18 internally. So there is a big difference between surgery or a  
19 surgeon and a proceduralist or a gastroenterologist doing  
20 procedures.

21 Q. Okay. And if we look at 9007A-112 and 113, we see the  
22 operative report that Dr. Huh for this procedure did.

23 A. We do.

24 Q. Okay. And there was some anesthesia used; is that right?

25 A. Yes, there was anesthesia used.

1 Q. What is MAC?

2 A. It's monitored anesthesia care. It's delivered by an  
3 anesthesiologist. And I think she received propofol, and  
4 whether a gastroenterologist can give propofol or not is state  
5 dependent. In the state of West Virginia and Virginia and  
6 many other states, it can only be administered by an  
7 anesthesiologist or they have anesthesia assistance.

8 Q. Okay. And if we look down towards the bottom of -- with  
9 the description, we see there was an active bleeding lesion  
10 kind of towards the last few sentences, possibly an AVM.

11 And I want to ask you about I injected the area -- there's  
12 an injection of some sort that is done.

13 A. Yeah. So what we can do -- whether you inject it or not  
14 is kind of, I think, preference. You know, it's a  
15 GI physician's preference.

16 Epinephrine is a drug that will take the vessel and will  
17 make it constrict, it will make it get tight, so it will  
18 decrease the amount of bleeding. Epinephrine is not meant to  
19 treat the bleeding alone. We have a lot of data saying  
20 epinephrine alone is not enough in GI bleeding.

21 So it's very appropriate for him -- he saw a bleeding  
22 lesion, he injected some epinephrine. It did decrease the  
23 amount of bleeding, didn't stop it. Again, you do not just  
24 use epinephrine in any endoscopic procedure. And then he  
25 placed that metallic clip over the AVM, and he stopped the

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1       bleeding immediately. So it was a good outcome.

2       Q. And that's what I wanted to ask you.

3             Did it appear that Dr. Huh found the source of the bleed?

4       A. He did. And he took care of it with epinephrine and two  
5       clips.

6       Q. Okay. And if we go to the patient tolerated the procedure  
7       well, what does that mean in -- in doctor speak?

8       A. Yeah. That is kind of a drop-down menu on our -- what we  
9       call the electronic medical record.

10            Basically the bottom line, it means the patient did well.  
11       Vital signs were stable. They didn't have any troubles with  
12       the sedation. The procedure went well. So there was no issue  
13       during the procedure.

14       Q. Okay. And this appears to be dictated -- I was looking  
15       for the date. It's on the next page.

16       A. It was dictated on 5/21.

17       Q. Okay. The day of -- it looks like the day of the  
18       procedure?

19       A. The day of the procedure, which is the day after she was  
20       admitted on the 20th.

21       Q. So Mrs. Knight saw Dr. Abdelgaber on the 20th, was  
22       referred to Dr. Huh in the evening of the 20th, and the very  
23       next morning Dr. Huh performed a procedure.

24            And did he stop and repair and treat that particular GI  
25       bleed at that point in time?

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1 A. Yes, he did.

2 Q. And did he treat it successfully in your opinion?

3 A. Yes.

4 Q. And did Mrs. Knight have any recurrence of a GI bleed,  
5 based on your review of the records, after May 21st of 2013?

6 A. No recurrence.

7 I do want to stipulate -- or say one thing. We did  
8 mention she had two units of blood overnight. They did give  
9 her another two units during that next day, so she had a total  
10 of four units of blood. I didn't want to give the impression  
11 that she only got two units. She got four units total.

12 Q. So she got two one day and two --

13 A. I believe two the next day. It's hard to tell the actual  
14 timing of it.

15 Q. Sure.

16 A. But, yeah, she had absolutely no bleeding after that was  
17 placed.

18 Q. And to a reasonable degree of medical and scientific  
19 certainty, is it your opinion that Mrs. Knight's GI bleed was  
20 successfully treated on May 21st, 2013?

21 A. Absolutely.

22 Q. Okay. Now, you noted that there were four total pints of  
23 blood provided or transfused for Mrs. Knight.

24 Now you've read the label or the data associated with the  
25 clinical trial for Pradaxa --

1 A. Yes.

2 Q. -- correct?

3 And there's sort of a distinction in how bleeds are  
4 characterized in that trial?

5 A. Yes. So major bleeding is characterized by needing two  
6 units of blood. And I think life-threatening bleeding is four  
7 units of blood.

8 I do want to say as a clinician, as a practicing  
9 gastroenterologist, that's not how we look at severe or  
10 life-threatening bleeding. I mean, every bleeding is  
11 important, and it -- and it requires vigilance. But, on the  
12 other hand, clinically that is not how we define -- I mean, it  
13 needed to be done -- defined for the study. But we as  
14 physicians look at vital signs. We look at whether people  
15 need to be in the ICU. So those are the factors we look at as  
16 physicians.

17 Q. Okay. Well, let me just ask a question as a practicing  
18 gastroenterologist.

19 At the time that Dr. Huh performed this procedure and  
20 returned her to the recovery room and had stopped the  
21 bleeding, was Mrs. Knight's life in danger or threatened by  
22 the GI bleed at that time?

23 A. No.

24 Q. If we go to 9007A-110 and 111, we see now Dr. Abdelgaber  
25 must have seen her after the procedure.



1 Does that appear to be what occurred?

2 A. So we're looking at 110?

3 Q. Yes.

4 A. Yes. So this is the discharge summary.

5 Q. Okay. And if we look down towards the bottom, we see that  
6 both a cardiologist and a gastroenterologist were consulted as  
7 part of this procedure that needed to take place.

8 A. Right, which is very reasonable.

9 Q. Because on the one hand, just like the jury has heard,  
10 there's the bleeding risk. With a GI bleed, that would be the  
11 gastroenterologist; is that right?

12 A. That is correct.

13 Q. And then on the other side you have sort of the stroke  
14 risk and the cardiologist who prescribed the anticoagulants or  
15 oversaw that on the other side, right?

16 A. That is correct.

17 Q. And is this a good thing that these physicians are talking  
18 to one another along with her primary care physician?

19 A. Yeah. You never want to -- you know, when you have two  
20 competing or two issues where you're struggling, you really  
21 want to get the expert on both ends to come together and give  
22 their opinion. And then you want to kind of come up with a  
23 consensus or an agreement with those physicians to come up  
24 with what the patient is discharged on, when they need to  
25 restart anticoagulation, whether they need to start

1 anticoagulation.

2 So it's very important to get both sides of the coin  
3 involved.

4 Q. Okay. And in the hospital course, the last couple  
5 sentences, just like you said, Dr. Shami, she was given  
6 another two units for a total of four units.

7 And what does it say about her hemoglobin?

8 A. Her hemoglobin stayed stable meanwhile.

9 Q. Okay. And it says that the number is 10.8.

10 Is that -- what does that number reflect? Is that okay or  
11 is that not okay?

12 A. That is her -- that is Mrs. Knight's baseline hemoglobin.

13 Q. Did you see anywhere in the records where Mrs. Knight's  
14 baseline hemoglobin was 14 or anything like that?

15 A. No. I saw a 12, I believe, in two thousand -- before 2008  
16 at some point, but I can't give you the precise date.

17 Q. And do those change over time as folks age?

18 A. Ah, they can. They can change over -- over. But she is  
19 chronically anemic, so she has chronic low levels of  
20 hemoglobin.

21 Q. Okay. And it says she remains stable.

22 I assume that was part of your opinion about whether or  
23 not she was successfully treated with this particular  
24 incident?

25 A. There is no doubt in my mind as a gastroenterologist who

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1 practices that she was -- you know, she had a GI bleed, it was  
2 taken care of, and that is now eliminated from the equation --

3 Q. Okay.

4 A. -- yes.

5 Q. And if we look at the next page, 9007A-111, we see the GI  
6 suggests that she can start back on only two of the three  
7 things related to triple therapy; is that correct?

8 A. That is correct. They chose to discontinue the Plavix.

9 Now, mind you, ideally the Plavix would be on -- you can  
10 say at that time frame it was almost four weeks that she was  
11 on it. But as her cardiologist mentioned before, ideally she  
12 would be on it longer.

13 Q. So after the May 2013 GI bleed, no more Plavix; is that  
14 correct?

15 A. That is correct.

16 Q. And --

17 A. And that was approximately four weeks, I think she is two  
18 days short of that, but that is the minimum amount of Plavix  
19 you want to give. Ideally you would give a longer duration.

20 Q. And after May of 2013 until Mrs. Knight's passing on  
21 September 2nd, 2013, she did not have any further GI bleeds,  
22 did she?

23 A. That is correct.

24 THE COURT: How much longer do you think your direct  
25 will be?

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1 MR. LEWIS: I probably have, Your Honor, maybe 15, 20  
2 minutes.

3 THE COURT: All right. Let's go ahead and take a  
4 recess now. We'll take a lunch break until 1:30.

5 Remember my instructions. Don't discuss the case.  
6 Don't deliberate. You can follow the same practice we did  
7 last week about coming and going from this room.

8 Doctor, you can step down. Just don't discuss your  
9 testimony with anybody. All right?

10 THE WITNESS: Thank you.

11 THE COURT: We'll take a recess until 1:30.

12 (Lunch recess taken at 12:27 p.m.)

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1 THE COURT: All right. Are we ready to resume?

2 MR. LEWIS: Yes, Your Honor.

3 THE COURT: Let's bring out the jury.

4 (Jury returned into the courtroom at 1:32 p.m.)

5 THE COURT: All right, you may be seated.

6 Counsel, you may resume your examination of the  
7 witness.

8 MR. LEWIS: May it please the Court, good  
9 afternoon, members of the jury.

10 BY MR. LEWIS:

11 Q. Dr. Shami, where we left off was discussing after the  
12 May, 2013, GI bleed experienced by Mrs. Knight. And, so, to  
13 orient us, I want to discuss some of the medical records and  
14 discussions from physicians that treated her after that  
15 point in time, and specifically, 9005-A, Page 5, which is  
16 August 29th, 2013.

17 A. I've got it.

18 Q. And this is a note from Dr. Gunnalaugsson; is that  
19 correct?

20 A. Yes, it is.

21 Q. And I want to kind of go over what Dr. Gunnalaugsson  
22 says at this point in time. And this is unfortunately a few  
23 days before Mrs. Knight passed. She came into the hospital  
24 to see her physician.

25 And in the section that we have pulled up, Dr.

1 Gunnalaugsson is commenting on the prior GI bleed; right?

2 A. Yes. He says, "Ms. Knight is an 84-year-old woman with  
3 a history of multiple medical problems. She was  
4 hospitalized with severe anemia due to GI bleed."

5 Q. And he goes on to say she was eventually surprisingly  
6 put back on Pradaxa and she had been off Plavix. So at this  
7 point in time in August of 2013, Mrs. Knight is on Pradaxa,  
8 off Plavix from the bleed event that took place in May of  
9 2013. And now Dr. Gunnalaugsson is suggesting not to take  
10 aspirin as well.

11 A. That is correct, yes.

12 Q. Does that -- in your view, does that express a concern  
13 about potential for bleed?

14 A. I mean, I think again, yes, he's kind of struggling, as  
15 I think the rest of the physicians are, about, you know,  
16 bleeding versus clot or thrombosis. And, obviously, in this  
17 case he mentions the severe anemia and GI bleeding, so,  
18 yeah.

19 Q. Okay. And then he goes on to say -- talks about the  
20 stent procedure, the percutaneous coronary intervention.  
21 That would be a stent?

22 A. Yes, usually. I mean, they can just dilate or stretch  
23 it but, yeah, she was -- in her case, she was stented.

24 Q. And then it indicated that, as we discussed, that  
25 Plavix was added to her therapy, her anticoagulant therapy

1 due to the stent. And Dr. Gunnalaugsson says was put on  
2 Plavix which probably triggered her bleed. So I want to ask  
3 you about that.

4 Based on what you've seen in the medical records, do  
5 you disagree with the treating cardiologist, Dr.  
6 Gunnalaugsson, that Plavix probably triggered the bleed?

7 A. I don't, I don't disagree, no. I can tell you that we  
8 know what -- we know what she was bleeding from and that's  
9 an AVM. And we also know again the one drug that was added  
10 after which she bled from was the Plavix. That's what I can  
11 tell you.

12 Q. And if we go to the next page, which is 9005-A, Page 6,  
13 Dr. Gunnalaugsson is describing what was sort of the  
14 assessment or plan that carries over from the prior page.  
15 But there's a note that says, "She will remain on Pradaxa  
16 since she is tolerating this right now."

17 Do you see where it says that?

18 A. Yes.

19 Q. Okay. So this is the same record where Dr.  
20 Gunnalaugsson, concerned about the bleed, takes away aspirin  
21 after Plavix has been taken away; is that right?

22 A. That is correct.

23 Q. Okay. So based on your experience -- and I think you  
24 maybe have already told the jury this. But when a doctor  
25 says someone is tolerating a medication, what does that mean

1 again?

2 A. Usually it can mean a few things. They're tolerating  
3 it from a side effect profile. So it can be simple things  
4 such as nausea, diarrhea, you know, it's not making them  
5 feel bad.

6 And in her case, I'm assuming he means from, you know,  
7 from a bleeding standpoint. She's tolerating it. She's not  
8 having anymore bleeding.

9 Q. And is it the case, based on your review of the medical  
10 records, that Mrs. Knight was not suffering, didn't  
11 experience a GI bleed or a bleed of any kind after May of  
12 2013?

13 A. That is correct.

14 Q. So I want to ask you some questions about the cause of  
15 Mrs. Knight's GI bleed, and in particular your opinions  
16 about that to a reasonable degree of scientific and medical  
17 certainty.

18 Is it your opinion that the source of the GI bleed was  
19 an AVM?

20 A. Absolutely.

21 Q. And do you hold that opinion to a reasonable degree of  
22 medical certainty?

23 A. I do.

24 Q. Do you also agree that like any anticoagulant  
25 medication, Pradaxa or even Plavix had some contribution?



1 Let's talk about Pradaxa.

2 So is it also your opinion that Pradaxa, like any  
3 anticoagulant medication, contributed in some way to the  
4 circumstances surrounding the bleed?

5 A. It can, yes.

6 Q. And is it your opinion that you can't disagree with Dr.  
7 Gunnalaugsson's opinion that the Plavix triggered it? Is  
8 that fair?

9 A. That's fair.

10 Q. And you hold those opinions to a reasonable degree of  
11 medical certainty?

12 A. I do.

13 Q. Now, a couple things about Dr. Ashhab's testimony.

14 Number one, Dr. Ashhab testified that there's some  
15 difference in the way someone experiences a bleed with  
16 Plavix versus a NOAC like Pradaxa or Xarelto or Eliquis.  
17 Are you familiar with any scientific literature that backs  
18 up that kind of statement?

19 A. Well, -- no. The answer is, no, there is no literature  
20 to back that up.

21 Q. And there was some discussion in Dr. Ashhab's testimony  
22 that there was an oozing versus a faucet. Is that something  
23 that you've ever seen in any of the literature?

24 A. I have never seen or -- kind of heard GI bleeding  
25 pertaining to that. I've heard the word "ooze." But there

1 is absolutely no data out there that says one anticoagulant  
2 causes oozing and an anti-platelet causes an oozing or a  
3 faucet. It's not a concept that we use in the literature  
4 and it's not a concept that I've ever heard of.

5 Q. Okay. Now, let me ask you this. As someone who is on  
6 the board of a major organization of gastroenterologists,  
7 who teaches medical students, who writes articles and goes  
8 to conferences, do you think something like that would have  
9 been discussed somewhere in your 16 years of your career if  
10 that were the case?

11 A. Yes.

12 Q. Now, I want to get to the -- I'm finished with that --  
13 the next opinion. And that relates to whether if Mrs.  
14 Knight had been on warfarin, some other different outcome  
15 would have occurred.

16 Now, just to back up and orient us, nothing in Mrs.  
17 Knight's experience with warfarin suggested she was on  
18 Plavix and warfarin and aspirin at the same time; is that  
19 right?

20 A. That is correct, that is, the records that we have  
21 available to us, yes.

22 Q. In fact, the records that we looked at this morning  
23 suggested doctors felt like they needed to make a choice  
24 between one or the other when she was on warfarin. Is that  
25 fair?

1 A. That is correct.

2 MR. CHILDERS: Judge, object to leading again.

3 THE COURT: All right. Refrain from leading.

4 MR. LEWIS: Sure.

5 BY MR. LEWIS:

6 Q. Do you have an opinion, Dr. Shami, to a reasonable  
7 degree of medical certainty as to whether or not if Mrs.  
8 Knight had been on warfarin instead of Pradaxa that she  
9 would have experienced some easier, lesser, or different  
10 kind of bleed?

11 A. No. And there's actually some literature to back that  
12 up.

13 Q. Okay. And that's what I want to talk about.

14 MR. LEWIS: Your Honor, Exhibit 5620-A is what we  
15 would offer to publish as a learned treatise. It's been  
16 provided to counsel for the plaintiffs.

17 MR. CHILDERS: I don't have any objection to her  
18 testifying about the article. It's not an exhibit  
19 obviously.

20 THE COURT: All right.

21 MR. LEWIS: May I publish?

22 THE COURT: You may.

23 MR. LEWIS: If we could publish Exhibit 5620-A.

24 BY MR. LEWIS:

25 Q. Doctor, is this one of the pieces of literature that

1 you reviewed in forming your opinions?

2 A. Yes.

3 Q. Okay. How did this article -- before we talk about it,  
4 how did this article inform your opinion about what we've  
5 just discussed?

6 A. So basically what the article did was look at patients  
7 who were on anticoagulation, so specifically Pradaxa or  
8 warfarin, who had major GI bleeds.

9 And the GI -- not GI bleeds, all bleeds -- my  
10 apologies. So there are GI bleeds. There are head bleeds.  
11 They can be bleeds in the body or peritoneum, so all-comers.

12 And what they did was they analyzed how easy it was to  
13 fix their bleed or stop their bleed as well as 30-day  
14 mortality, which means their survival of 30 days.

15 What they saw out of those major bleeding patients in  
16 those that occurred due to non-traumatic reasons, in other  
17 words, they weren't in a car accident, they didn't fall down  
18 the stairs, the bleeding just sort of occurred spontaneously  
19 because of, you know, of the reason and being on  
20 anticoagulants, of those people, they were actually able to  
21 control the bleeding from the Pradaxa a little bit easier  
22 than the Coumadin.

23 The other thing is the mortality rate was lower with  
24 the Pradaxa than it was the warfarin or the Coumadin.

25 So I think this just kind of demonstrates to me that I

1 don't think we could say there would be a difference in  
2 outcome if Ms. Knight was on warfarin or if she was on  
3 Pradaxa. I mean, I just don't think you can say that  
4 without a reasonable degree of doubt.

5 Q. Okay. And, so, just to step back a little bit, this  
6 article is what's called a peer-reviewed article?

7 A. It is a peer-reviewed article.

8 Q. At a real high level for the jury, I don't think  
9 they've heard a lot about what that means. Are you able to  
10 explain sort of to a common person like me what that means?

11 A. Sure. So a peer-reviewed article -- so, you know, we,  
12 we come up with ideas to test -- come up with a hypothesis  
13 and then the data. And this -- these papers take weeks,  
14 actually months to years.

15 And once they're put together, the data is put together  
16 and the conclusions are drawn and you come up with the,  
17 write the manuscript, you -- that's not enough to just get  
18 it published.

19 And the reason for that is if we just are able to  
20 publish anything, then we would have all of this data that's  
21 not really relevant or, or not formulated in a proper way.

22 So what they usually do for these journals is they have  
23 a group of physicians when you submit this manuscript and  
24 they have a group of physicians review it.

25 If they feel like it's a good enough article, then it

1 will get accepted and published.

2 Often times even if it gets accepted and published, the  
3 review panel will ask them to make changes or ask questions  
4 to, to revise the manuscript. So it is an in-depth process  
5 for it to be peer-reviewed.

6 Q. And is it also appropriate in a peer-reviewed article  
7 to discuss both some potential scientific limitations and  
8 conflicts of interest?

9 A. Absolutely.

10 Q. And is that done in this article?

11 A. It is.

12 Q. If we look at 5628, Page 7, without getting into  
13 detail, but the authors outline some of the scientific  
14 limitations that the peer-reviewing folks have to consider  
15 as part of the science?

16 A. Yes. And any time we have a peer-reviewed manuscript,  
17 it's always proper to put the limitations so that the  
18 readers realize that it's not kind of the -- the limitations  
19 or the down sides, the weaknesses.

20 And in this case one of them was that it was a  
21 retrospective study. In other words, it was a study where  
22 all the data -- the patients were taken care of. All the  
23 data was there. And you have to go in hindsight and pick  
24 out all that data. So that's retrospective. So that is one  
25 limitation of the study.

1 Q. Sure. But it passed peer-review if it got published?

2 A. Absolutely.

3 Q. And then if we go to the next page, 5628, we see that  
4 there are various disclosures including that some of the  
5 authors received money from Boehringer?

6 A. Absolutely.

7 Q. And that's appropriate to disclose that; right?

8 A. You have to disclose that.

9 Q. But if we scroll up just above "Disclosures," we see  
10 that the peer-review folks approved this summary if we could  
11 highlight the "Summary." This is basically the gist of the  
12 article or the ultimate conclusion of the article.

13 A. So in summary, patients with different types, locations  
14 and causes of dabigatran or Pradaxa associated major bleeds  
15 can be managed effectively with supportive therapy, with  
16 similar or better outcomes than patients with warfarin  
17 associated bleeds. This, together with the ease of  
18 administration, adds to the advantages of treatment with  
19 dabigatran, or Pradaxa, in the different subgroups discussed  
20 here.

21 Q. And based on what you saw from Dr. Ashhab's testimony  
22 earlier in this trial that you read, did he cite to any  
23 articles that suggested that he was right about warfarin  
24 making a difference?

25 A. No.

1 Q. Okay. Thank you. Last subject. Dr. -- last subject  
2 on this particular point.

3 Dr. Ashhab also suggested that Mrs. Knight was  
4 over-anticoagulated on Pradaxa at the time of the GI bleed.  
5 So I want to ask you a couple questions about that.

6 First of all, do you agree with that statement?

7 A. No.

8 Q. Did you see anywhere in any medical record around the  
9 time of Mrs. Knight's GI bleed where any physician said she  
10 had too much Pradaxa in the blood or was  
11 over-anticoagulated?

12 A. No.

13 Q. Is that a term that you are even familiar with when it  
14 comes to that sort of assessment?

15 A. We don't use -- we use "supra" which is high or, or --  
16 you know, I mean, but "over-anticoagulated," no, especially  
17 in a drug where no, you know, the therapeutic range is, is  
18 not established.

19 Q. You have treated folks who have been on warfarin?

20 A. Yes, I have.

21 Q. And we know that with warfarin -- we've talked about  
22 this -- that there's a therapeutic range. And if you're too  
23 high, a 6, 7, 8, that's a bleed risk. And so sometimes  
24 physicians will hold the medication when that occurs. Is  
25 that correct?



1 A. Correct.

2 Q. And you've done that before?

3 A. Absolutely.

4 Q. We know in this instance that after the bleed event,  
5 there was one medication that was continued. That was  
6 Pradaxa; right?

7 A. Yes.

8 Q. Would you continue a medication if you thought that the  
9 patient had too much of that medication in your -- in their  
10 blood?

11 A. No, I would not.

12 Q. And we know that Plavix was discontinued after Mrs.  
13 Knight's bleed.

14 A. It was discontinued after her bleed, correct.

15 Q. Okay. The last subject relates to whether Pradaxa or  
16 the GI bleed experienced by Mrs. Knight in May of 2013  
17 contributed to her passing later that year.

18 And I think you've already explained that it's your  
19 opinion to a reasonable degree of medical certainty that  
20 neither the Pradaxa nor the GI bleed contributed to her  
21 passing later that year?

22 A. That is correct.

23 Q. And let's look at a couple of the records that you  
24 asked me to pick out to support that opinion.

25 A. Absolutely.

1 Q. 9007-A-146, which is admitted into evidence, is from  
2 August 23rd of 2013?

3 A. That is correct.

4 Q. Do you recall this record?

5 A. I do.

6 Q. Okay. And this is Dr. Snively referred by Dr.  
7 Abdelgaber in August. And do you see where it says "reason  
8 for consultation"?

9 A. Yes, I do.

10 Q. "Elevated troponin." I think the jury may have heard  
11 something about that earlier. Do you know what that  
12 generally means?

13 A. Yeah. So usually troponin levels can be elevated when  
14 you have heart damage. So the -- you know, it can occur  
15 with heart failure as well. But usually if you have  
16 significant heart damage, those levels will be fairly high.

17 So it's, it's technically a, a blood test. And it's --  
18 we do it all the time to make sure somebody is not having a  
19 heart attack.

20 Q. And elevated means that there's a concern or potential  
21 sign that a heart attack --

22 A. Correct.

23 Q. -- is being experienced?

24 A. That's correct.

25 Q. Okay. And the jury is going to hear from another

1 cardiologist later, maybe even later today. So we won't get  
2 into too much more detail other than to look at the past  
3 medical history down at the bottom of that page.

4 And you see that there is a recitation that goes -- it  
5 starts on that page and actually rolls over to the next page  
6 of many of the things. And do you recall looking through  
7 the medical records and seeing that Mrs. Knight was  
8 struggling with many different conditions?

9 A. Yes.

10 Q. Okay. And to the best of your recollection, are these  
11 the conditions that are listed on Page 9007-A-147 and the  
12 page before it?

13 A. Yes.

14 Q. Okay. I want to go back to the page before it. To be  
15 fair, one of the things listed on number two is a history of  
16 GI bleeding secondary to gastritis and what, kind of what  
17 you've already told us, --

18 A. AVM.

19 Q. -- AVM.

20 A. Correct.

21 Q. So this doctor who is treating Mrs. Knight at this time  
22 is aware, it appears, of this past history. Is that fair?

23 A. That is correct.

24 Q. And that's important to be aware of past history. As a  
25 treating physician and getting referred to a patient, you

1 want to figure that out, what else you've got to worry about  
2 essentially; right?

3 A. Absolutely.

4 Q. And if we go to the plan which is on 148, let's look at  
5 this. And this is Dr. Snavelly in the face of the  
6 information he's collected on Mrs. Knight.

7 What does it say about Dr. Gunnalaugsson's view and the  
8 medication that she had earlier for anti-platelet therapy?

9 A. So it says clearly that he did not want her back on  
10 Plavix due to the history of gastrointestinal bleeding. And  
11 --

12 Q. And -- I'm sorry. Go ahead.

13 A. "We will keep her -- we will simply keep her on  
14 low-dose aspirin along with the Pradaxa because I do not  
15 think that the Pradaxa could be held in the long-term given  
16 her multiple issues with blood clots."

17 Q. So at this point in time, the decision was made,  
18 despite the history, to keep her on Pradaxa and make sure  
19 that she's not going to go back on Plavix even though she  
20 had some signs of a potential heart attack.

21 A. That is correct. She needed to be on an anticoagulant.

22 Q. Thank you for that. And I just wanted to spend a  
23 couple moments --

24 MR. LEWIS: I'm going to move for the admission  
25 first of Defendant's Exhibit 9013-B. That's one that has

1 not been admitted. It is a subset of home healthcare  
2 records.

3 MR. CHILDERS: No objection, Your Honor.

4 THE COURT: It's admitted.

5 (Defendant's Exhibit Number 9013-B admitted into  
6 evidence.)

7 MR. LEWIS: Permission to publish, Your Honor.

8 THE COURT: You may.

9 BY MR. LEWIS:

10 Q. And let me just step back for a minute. As part of  
11 your work in this case, did you review home healthcare  
12 records related to Mrs. Knight's circumstances?

13 A. I did.

14 Q. And can you -- I don't think the jury has heard a lot  
15 about home healthcare and what happened with Mrs. Knight  
16 over time. So could you kind of just describe a little bit  
17 about the time frame that may have covered and what home  
18 healthcare really is?

19 A. Yeah. My understanding looking at the records -- so  
20 home health is -- so there's two kinds of, of assistance.

21 Home health usually means that somebody comes out to  
22 the house as often as needed to check vital signs, to check  
23 blood or to check on the patient, along with family members  
24 being at home.

25 And then if you're in a rehab center, in-patient rehab

1 center, that's more of a, you know, daily -- it's not a  
2 hospitalization at all but it's, it's a step up from home  
3 health.

4 And in her situation, she's been in and out of skilled  
5 nursing facilities, as well as have intermittent home health  
6 the entire time that we've had records available.

7 Q. And I just want to pick out one particular circumstance  
8 and then maybe look at more of a summary which would be on  
9 Page 9013-B-1539.

10 A. Okay. Mr. Lewis, I'm sorry. I'm not following. Which  
11 tab was it?

12 Q. 9013-B.

13 A. I think I'll look up here.

14 Q. Okay. It's pretty small and I apologize. The home  
15 healthcare reports are fairly lengthy when the folks come to  
16 the house. Is that fair?

17 A. They are. They're difficult to read as well.

18 Q. And as part of the home healthcare, are they doing more  
19 than just helping around the house? Are they actually doing  
20 some medical stuff?

21 A. So they will check vital signs, as I was saying before.  
22 They can check labs. They can help with physical therapy,  
23 occupational therapy. So it really depends on what the  
24 patient needs.

25 Q. Could you blow that up the best you could? I

1 understand the print is really, really small and hard to  
2 read. I apologize for that.

3 But in this particular instance, this is from January  
4 of 2012. So this would be before Mrs. Knight had her stent  
5 procedure. But if -- I think this is one of the ones that  
6 you had pointed out. When the home healthcare provider  
7 showed up at the house, Mrs. Knight had had a burning pan on  
8 the stove.

9 A. Yeah. Unfortunately, she had, you know, an unsteady  
10 gait. There was a pan on the stove which, again, sort of  
11 suggests issues with maybe potentially memory which has been  
12 in her records. She's had some documentation of dementia.  
13 So the, the whole question of her safety has come up in this  
14 note as well in a, in a few areas.

15 Q. Okay. And -- thank you. I'm finished with that.

16 We prepared and you've looked at and sort of looked at  
17 the backup medical records, a summary of some of the  
18 conditions that Mrs. Knight had over time and, and --  
19 including some of the hospitalizations.

20 Can you pull up the demonstrative of the list?

21 And if you look on the left-hand side, we see some of  
22 the conditions that were problems or issues for Mrs. Knight  
23 over the entire course of the records that you looked at.  
24 Is that fair?

25 A. That is correct.

1 Q. And would you agree that the conditions listed on the  
2 left side, these are things that she had before she even  
3 took Pradaxa?

4 A. Yes. And the list we have here is just 2008 to 2011.

5 Q. So --

6 A. And I think prior to, yes.

7 Q. And several hospitalization stays. There were multiple  
8 days, particularly with her heart condition. Is that right?

9 A. That is correct.

10 Q. And the longest was the clot that we've looked at  
11 earlier today?

12 A. She was there for 15 days, yes.

13 Q. So when we get to the point in time of September of  
14 2013 and Mrs. Knight passed away, there were physicians  
15 on-site that had to make the decision as to the cause of her  
16 death.

17 A. That is correct.

18 Q. This has been admitted into evidence as Exhibit 9001.  
19 Are you familiar with -- unfortunately familiar with a death  
20 certificate, the legal document where a doctor has to  
21 indicate the cause of someone passing?

22 A. Unfortunately, yes.

23 Q. And do you see that this is a document that was signed  
24 by Dr. Abdelgaber after Mrs. Knight passed away in  
25 September?



1 A. That is correct.

2 Q. And he indicates the, the immediate cause. Do you see  
3 where it says "cardiopulmonary arrest"?

4 A. I do.

5 Q. And do you -- based on your review of the medical  
6 records to a reasonable degree of medical certainty, is that  
7 consistent with what you have seen -- obviously, Dr.  
8 Abdelgaber was on-site and present.

9 A. Sure.

10 Q. But is that consistent with what you saw in the medical  
11 records as immediate cause of Mrs. Knight's passing?

12 A. Yeah. If you look at the medical records, she  
13 complained, unfortunately, of chest pain, right-sided chest  
14 pain. And I think by the time the EMT docs got there, she  
15 needed a breathing tube. So the chest pain is one, one kind  
16 of clue.

17 The second one is that her troponin levels when she  
18 arrived were elevated. They were significantly elevated,  
19 which tells me she's had heart damage. So I don't doubt  
20 that diagnosis at all.

21 Q. And Dr. Abdelgaber goes on to list three things that  
22 may be underlying causes. If you read to the left, that's  
23 sort of the place where underlying causes, acute myocardia  
24 infarction, --

25 A. Atherosclerotic coronary artery disease and

1 hyperlipidemia.

2 Q. And, again, to a reasonable degree of medical  
3 certainty, based on your review of the medical records, is  
4 that consistent and do you agree with Dr. Abdelgaber's  
5 listings here?

6 A. Yes.

7 Q. And then there are other significant conditions that  
8 are listed under that. And are you familiar with the  
9 abbreviations that you see?

10 A. Yes. Congestive heart failure, CHF. Hypertension or  
11 high blood pressure is HTN. CHD is chronic kidney disease.  
12 And dementia is dementia, memory loss.

13 Q. And based on your review of the records in this case,  
14 was there support for those findings by Dr. Abdelgaber to a  
15 reasonable degree of medical certainty?

16 A. Yes.

17 Q. Okay. And so I want to ask you about this. Do you  
18 agree with Dr. Abdelgaber's decision not to put on this list  
19 GI bleed or Pradaxa?

20 A. Yes.

21 Q. And would you state -- would you agree to a reasonable  
22 degree of medical certainty that neither Pradaxa nor the GI  
23 bleed from May of 2013 caused Mrs. Knight's passing?

24 A. Absolutely.

25 Q. Doctor, thank you for your time. That's all I have for

1 now.

2 A. Thank you.

3 THE COURT: All right.

4 MR. CHILDERS: Could I just have a few minutes to  
5 set up?

6 THE COURT: Yes. We'll take about a five-minute  
7 recess before we start the cross-examination.

8 (Recess taken from 2:08 p.m. until 2:15 p.m.)

9 (Jury not present)

10 THE COURT: All right, Mr. Lewis, I understand  
11 that there is a matter we need to address before.

12 MR. LEWIS: Yes, Your Honor. Thank you.

13 The Court is still considering the motion for directed  
14 verdict and, in particular, related to the Medication Guide.  
15 I'm concerned that more evidence on that issue, including  
16 reciting the deficiencies as they've done with a lot of  
17 witnesses in the case, is going to compound the problem that  
18 I think we already have on that particular issue.

19 And I don't really know how to address it, but I wanted  
20 to raise it with the Court now before the jury comes in on  
21 how to, how to deal with that or whether we can preclude  
22 that kind of an examination.

23 THE COURT: Well, who's going to cross-examine?

24 MR. CHILDERS: I am, Your Honor.

25 THE COURT: Do you expect to ask her specific

1 questions about the adequacy of the Medication Guide?

2 MR. CHILDERS: I don't, I don't expect to ask her  
3 is it adequate, is it inadequate, anything like that. I do  
4 expect to ask her what's in it, what's not in it. I believe  
5 she was asked on direct about the label and the Medication  
6 Guide. So I think I have to follow up on that.

7 THE COURT: Well, first, I think he's permitted to  
8 ask what's in, what's out. What you raised in your motion  
9 was the preclusion of a claim based on the alleged  
10 defectiveness, inadequacy of the Medication Guide itself as  
11 a warning.

12 My understanding, and there doesn't appear to be any  
13 dispute, is that under the federal regulations, the  
14 Medication Guide is not subject to the unilateral change  
15 that the label is subject to.

16 And it seems clear to me that both parties recognize  
17 the case law from *Wyeth* and these subject cases has focused  
18 on the labeling and the procedure by which a manufacturer  
19 can unilaterally alter a label consistent with the same  
20 regulations.

21 And I didn't recall -- my recollection was that  
22 plaintiffs agreed that the Medication Guide was not subject  
23 to unilateral modification, that the Medication Guide had to  
24 go through an approval process. And, therefore, they  
25 weren't basing a claim of warning defect based on the

1 failure to change the Medication Guide.

2 MR. CHILDERS: That's correct, Your Honor. It's  
3 just evidence of what was and what wasn't told to Ms.  
4 Knight.

5 MR. LEWIS: That's the -- see, here's the problem,  
6 Your Honor. The, the evidence of what's in, not in the  
7 Medication Guide in making that presentation to the jury  
8 that there's something missing from that, from the  
9 Medication Guide is pre-empted. That piece of their case is  
10 pre-empted.

11 THE COURT: I think there's a difference between  
12 saying a claim based upon a failure of the Medication Guide  
13 to constitute a sufficient warning is different from saying  
14 what's in the Medication Guide, what's not in the Medication  
15 Guide.

16 MR. LEWIS: But if there's no claim that can be  
17 had on what's in or not in the Medication Guide, then  
18 there's no relevance under 402 and it's unfairly prejudicial  
19 under 403 to even allow an examination or argument to that  
20 effect. The, the -- I'm sorry.

21 THE COURT: Go ahead.

22 MR. LEWIS: I was just going to say that's, that's  
23 why there's a real problem with how they've presented their  
24 case because they've presented their case as if there's a  
25 problem with the Medication Guide because there's not stuff

1 in there that ought to be. And if you're going to present  
2 your case that way and make that argument or infer that to  
3 the jury, that's pre-empted. That's what the law doesn't  
4 permit.

5 MR. MOSKOW: Your Honor, may I ask the witness be  
6 excused before I make my argument?

7 THE COURT: Yes. You will have to step down.

8 THE WITNESS: Sure, absolutely.

9 THE COURT: Why don't you go through here and shut  
10 the door.

11 THE WITNESS: Yes.

12 (The witness, Vanessa Shami, exited the courtroom.)

13 THE COURT: All right. I've asked my law clerk to  
14 escort her down the hall.

15 MR. MOSKOW: Thank you very much, Your Honor.

16 To be clear, the issue essentially raised on direct but  
17 which is part and parcel of this entire case, is that the  
18 only warnings the defendants can point to that they actually  
19 gave to the Knight family are what's in the Medication  
20 Guide.

21 So identifying information that is either in the label  
22 or was in internal company documents within the knowledge of  
23 BI that has not been given to the Knight family is fair game  
24 for our failure to warn claim.

25 And this witness has now put herself out on a ledge

1 where she says that the label adequately warns of the risks  
2 of the drug. And now she's going to be entitled to sit  
3 through cross-examination and identify what is in there and  
4 what isn't, what the company knows, what it doesn't know,  
5 and whether or not they properly advised the Knight family  
6 of those issues.

7 MR. LEWIS: Again, Your Honor, the testimony on  
8 direct doesn't change the legal analysis on what they can  
9 and cannot claim or present in the case. Let me give the  
10 Court another example.

11 There's a well established body of precedent that says  
12 you cannot make a claim or infer that there was fraud on the  
13 FDA. It's called Buckman pre-emption, very, very commonly  
14 comes up in these types of pharma cases as well.

15 That doesn't preclude the defendant from saying we gave  
16 all of the stuff to the FDA that they needed to get. But  
17 the plaintiff cannot come into the case and say, "Oh, yeah.  
18 Well, you committed a fraud on the FDA when you did that."  
19 That piece of the case is barred by federal pre-emption.

20 THE COURT: Well, I'm going to I guess effectively  
21 deny your request to limit the scope of the  
22 cross-examination. I believe they can cross-examine her  
23 about what is in the Medication Guide, what is not in the  
24 Medication Guide.

25 I have indicated and I will confirm that I think the

1 appropriate way to address the Medication Guide and the  
2 evidence about it is to explain what arguments are permitted  
3 or not permitted concerning the claims as they might be  
4 connected to the Medication Guide. So that's the way I  
5 intend to deal with it.

6 MR. LEWIS: Thank you, Your Honor.

7 THE COURT: Okay.

8 MR. MOSKOW: Thank you, Your Honor.

9 (The witness, Vanessa Shami, returned into the  
10 courtroom.)

11 THE COURT: Let's bring the jury out.

12 (Jury returned into the courtroom at 2:25 p.m.)

13 THE COURT: All right, you may be seated.

14 Plaintiffs may cross-examine the witness.

15 MR. CHILDERS: Thank you, Your Honor.

16 CROSS EXAMINATION

17 BY MR. CHILDERS:

18 Q. Good afternoon, Doctor.

19 A. Good afternoon.

20 Q. Just toward the end of your direct examination you  
21 spent quite a bit of time talking about medications that  
22 Betty Knight had been on. Do you recall that?

23 A. Yes, I do.

24 Q. And, in particular, one of the things that you talked  
25 about was this chart that you called "Pradaxa no stroke or



1 bleed complications." Right?

2 A. That is correct.

3 Q. And you pointed out on here that, in particular, Ms.

4 Knight was started on Plavix in April, 2013; right?

5 A. That is correct.

6 Q. I just want to make sure the jury is, is clear on this.

7 It's not your opinion that Plavix caused this bleed, is it?

8 A. All I'm saying is that the, the difference between

9 those 18 months and whatever led to the bleed was the

10 addition of Plavix.

11 Q. That's not my question. My question is it's not your

12 opinion that Plavix caused Ms. Knight's bleed; correct?

13 A. Correct.

14 Q. Okay. You don't have any opinion as to whether any of

15 the medications that Ms. Knight was taking caused her bleed;

16 isn't that right?

17 A. My opinion is that any of them could have caused

18 bleeding. I think the cause of bleed -- I've made this very

19 clear in the past -- is the AV malformation.

20 Q. Ma'am, you don't have any opinion about whether

21 aspirin, Plavix, or Pradaxa played any part in Betty

22 Knight's bleed in May of 2013, do you?

23 A. It potentially could have contributed to it.

24 Q. Do you recall we met before, you and I, --

25 A. I do.

1 Q. -- in Charlottesville?

2 A. I do.

3 Q. And I took your deposition; correct?

4 A. Yes, you did.

5 Q. And before the deposition you prepared a report that  
6 was given to me so that I could ask you questions; right?

7 A. Absolutely.

8 Q. And before the deposition, you raised your hand like  
9 you did here in court and said, "I swear or affirm that I  
10 will tell the truth." Correct?

11 A. Absolutely.

12 Q. Okay. And do you recall in your deposition that I  
13 asked you --

14 MR. LEWIS: Your Honor, could I get a page and  
15 line number?

16 THE COURT: Certainly.

17 MR. CHILDERS: I'm happy to -- may I bring one up  
18 to the witness, Your Honor?

19 THE COURT: You may.

20 BY MR. CHILDERS:

21 Q. I'll tell you exactly where I am. Okay?

22 A. Okay.

23 Q. Do you recognize that as a copy of your deposition?

24 A. I do.

25 Q. Have you seen it before?

1 A. I have.

2 Q. Probably read it before you came here today; correct?

3 A. A while ago, yes.

4 Q. Okay. If you look on Page 147, --

5 A. I see it.

6 Q. Actually, you know what. Let's, let's start at 146.

7 Do you see I asked you at line 20, "I'm asking you if you  
8 believe that Plavix played any part in her bleed."

9 And you answered, "I can't tell you."

10 Correct?

11 A. Absolutely.

12 Q. And then on the following page on Page 147 I asked you,  
13 "Can you tell me if Plavix -- her being on Plavix didn't  
14 contribute in any way?"

15 And you said, "I can't tell you."

16 Right?

17 A. Correct.

18 MR. LEWIS: Objection, Your Honor. She hasn't  
19 said anything inconsistent with either one of those things.

20 THE COURT: Well, I'll leave that to the jury.  
21 Overruled.

22 BY MR. CHILDERS:

23 Q. And then I asked you, "Same question for aspirin. Can  
24 you tell me that didn't contribute to her bleed?"

25 And you said, "No."

1 Correct?

2 A. Yes.

3 Q. And then I asked you, "Can you tell me that any one of  
4 them did contribute to Ms. Knight's bleed?"

5 And you answered, "No. I think she had an AVM that  
6 bled."

7 Correct?

8 A. That is correct.

9 Q. And then my follow-up question to that was, "And  
10 whether or not aspirin, Plavix, or Pradaxa or any  
11 combination of those drugs played a part in the bleed, you  
12 don't have an opinion."

13 And you answered, "That's correct."

14 Right?

15 A. I did answer that here.

16 Q. And that's your opinion today; correct?

17 A. My opinion is no different than what I just mentioned  
18 before. It's exactly the same. She bled from an AVM and  
19 I've been very --

20 Q. Understood. But you don't have an opinion that Pradaxa  
21 or Plavix or aspirin or any combination of those drugs  
22 played any part in that bleed; correct?

23 A. You just read the deposition.

24 Q. Is that what you told me in the deposition, ma'am?

25 A. Yes.

1 Q. Okay. And that's what you're going to tell the jury  
2 here today; correct?

3 A. Sure.

4 Q. Despite the fact that you talked about all these  
5 medicines and showed them this chart, you don't have an  
6 opinion that Plavix caused Ms. Knight's bleed; right?

7 A. Correct. And that chart is very relevant to show the  
8 jury the sequence of medications that were added on.

9 Q. Before you came here today, you billed 127 hours of  
10 time working on Pradaxa in general and Pradaxa in this case;  
11 correct?

12 A. Correct.

13 Q. Almost 60 hours of that was just this case, Betty  
14 Knight's case; correct?

15 A. That is correct.

16 Q. And after spending all of that time working on this  
17 case, you can't tell the jury if even one of the medications  
18 Betty Knight was taking played any part in her bleed;  
19 correct?

20 A. There's nobody that's going to be able to tell you  
21 which one, if not one, two, or three of them, contributed to  
22 the bleed.

23 Q. Ma'am, I'm not sure you heard my question. My question  
24 was, you can't tell the jury that any one of them or any  
25 combination of them played any part in the bleed. That's

1 what you told me when I took your deposition. Correct?

2 A. That's not quite but --

3 Q. Do you want me to read it again?

4 A. Go ahead.

5 Q. Okay. The question, "Whether or not aspirin, Plavix or  
6 Pradaxa or any combination of those drugs played a part in  
7 the bleed, you don't have an opinion."

8 And what was your answer?

9 A. "No."

10 Q. I believe your answer was, "That's correct." Right?

11 A. Which page are you on now?

12 Q. Page 147 that we just read.

13 A. Okay. That's correct, yes.

14 Q. You're not telling the jury today you have a different  
15 opinion, are you?

16 A. I have not suggested one bit. The jury has heard that  
17 I think she bled from an AVM. She was --

18 Q. And you don't -- I'm sorry. Go ahead.

19 A. No, go ahead. I have not been inconsistent at all  
20 today.

21 Q. But you don't believe any medication played a part in  
22 that AVM bleed; correct?

23 A. It could have.

24 Q. You don't have an opinion that any one of them did,  
25 though; correct?

1 A. They could have.

2 Q. You don't have an opinion that one of them did to a  
3 reasonable degree of medical certainty, do you, ma'am?

4 A. No.

5 Q. Okay. You can't say putting Betty on Plavix caused her  
6 bleed; right?

7 A. That is correct.

8 Q. You can't say that Pradaxa did not cause her bleed;  
9 correct?

10 A. I don't think you can say it did cause her bleed.

11 Q. You can't say that it did not; correct?

12 A. Correct.

13 Q. Okay. Do you agree that the Pradaxa label itself --  
14 you've reviewed those labels; right?

15 A. I have.

16 Q. Do you agree that label says Pradaxa can cause  
17 bleeding; correct?

18 A. Absolutely.

19 Q. And you agree that Pradaxa can cause what would  
20 normally be insignificant malformations or lesions or  
21 fissures in the GI tract to become major or life-threatening  
22 bleeds; right?

23 A. They could. It definitely can.

24 Q. Okay. And you think that Ms. Knight, Betty, had a  
25 malformation like that, an AVM; correct?

1 A. Yes.

2 Q. You told us that's where she bled; right?

3 A. Correct.

4 Q. I think she had that AVM for several years before it  
5 bled; correct?

6 A. It's, it's possible that she had that one or if not  
7 more. Usually patients don't just have -- many times, about  
8 40 percent of the time if they have one AVM, they can have  
9 numerous AVMs. And she has risk factors for those AVMs  
10 including age, renal insufficiency, and cardiac issues.

11 Q. How many AVMs did Dr. Huh find on the colonoscopy he  
12 did?

13 A. One. But as you saw in my, my slide prior to this when  
14 I opened up, we're just covering a very small portion of the  
15 bowel when we do endoscopy. The entire small bowel which is  
16 actually many, many feet is left uncovered. So we are  
17 absolutely not taking a look at the entire GI tract.

18 Q. So when you say she may have had more than one AVM,  
19 that's just a guess; right?

20 A. Absolutely.

21 Q. Okay. You don't have any evidence that she had more  
22 than one AVM; right?

23 A. I do not.

24 Q. Okay. Even though you think that Betty had that AVM  
25 for several years, you agree with me that she never noticed



1 blood coming from her rectum until May of 2013; right?

2 A. That's incorrect.

3 Q. But she -- you believe she noticed red blood coming  
4 from her rectum prior to May of 2013?

5 A. Blood can be dark.

6 Q. Okay.

7 A. And blood can be red.

8 Q. Okay.

9 A. So red blood, you're correct; dark blood, you're  
10 incorrect.

11 Q. Red blood would be evidence of a frank bleed, one  
12 that's happening right now; right?

13 A. Or it could be -- yes. The answer is "yes."

14 Q. She never had that prior to May of 2013, did she?

15 A. She did not have red blood, correct.

16 Q. And that wasn't just from her. None of her doctors  
17 ever noticed she had red blood coming from her rectum until  
18 May of 2013; right?

19 A. You are correct.

20 Q. All right. It seemed to me that you had sort of five  
21 things that you wanted to tell the jury while you were  
22 testifying today. Let me see if I can get them right.

23 A. Sure.

24 Q. The jury has seen my handwriting before and it's not  
25 great but I hope you guys can follow it.

1           The first one was: Was warfarin safe and effective for  
2 Betty Knight? Right? Wasn't that the first one you talked  
3 to Mr. Lewis about?

4       A.    Yes, we did.

5       Q.    Okay. You don't manage atrial fibrillation patients in  
6 your practice; right?

7       A.    I have numerous patients with atrial fibrillation, but  
8 I do not directly manage them, correct.

9       Q.    When you say you have numerous patients with atrial  
10 fibrillation, that's the same as saying you have numerous  
11 patients who have cancer but you're not treating their  
12 cancer; right?

13       A.    Not quite correct but -- because I do endoscopic  
14 ultrasound and I inject things into cancers. So that's  
15 incorrect.

16       Q.    Ma'am, do you remember I asked you that question at  
17 your deposition?

18       A.    Uh-huh.

19       Q.    Do you want to look at it again? If you'd go to Page  
20 35.

21       A.    Sir, I now since that deposition inject fiducials and  
22 that's a new procedure I do. So I didn't feel like it would  
23 be honest for me to preclude that.

24       Q.    That's something that you just started doing?

25       A.    Absolutely started doing.

1 Q. Okay. But you do agree at the time of your deposition  
2 saying you treat AFib patients with the same --

3 A. I never placed a fiducial back then.

4 THE COURT: Wait until he finishes his question.

5 THE WITNESS: Absolutely.

6 BY MR. CHILDERS:

7 Q. I didn't hear what you said, ma'am.

8 A. You go ahead.

9 Q. At the time of your deposition you agreed with me that  
10 saying you treat atrial fibrillation patients is the same as  
11 saying you treat cancer patients but you don't actually  
12 manage any of their care; right?

13 A. Absolutely.

14 Q. Okay. You don't typically calculate a patient's time  
15 in therapeutic range on warfarin or Coumadin, do you?

16 A. No.

17 Q. But you told the jury that you did that here for Betty  
18 Knight's case; right?

19 A. I looked at the INRs.

20 Q. And -- but, but if I understood you correctly, I think  
21 you said you looked at all the INRs of the chart and you  
22 just added up how many were in range and how many were out  
23 of range and compared them? Is that right?

24 A. That is correct.

25 Q. You know that's not how you calculate time in

1 therapeutic range; right?

2 A. No, but we're demonstrating a point that she cannot --  
3 it's very hard for her to stay in that 2 to 3 range.

4 Q. Time in therapeutic range is an actual time when a  
5 person stays in range. It's not the number of tests they  
6 have. Correct?

7 A. Correct.

8 Q. And so you told the jury it was only about 40 percent  
9 based on the way you did it which is not actually  
10 calculating the time in therapeutic range; right?

11 A. I said less than 50 percent, A; and, B, that is the  
12 number of times I calculated based on the INR. So that is  
13 very consistent with what I've said.

14 Q. If you calculate the time in therapeutic range  
15 correctly by using the amount of time in therapeutic range,  
16 would it surprise you to know Betty was actually in range  
17 about 60 percent of the time?

18 A. I wouldn't be surprised but that's below our goal of  
19 70 percent.

20 Q. Now, in the RE-LY trial patients who were on warfarin  
21 that they compared Pradaxa to, they were less than  
22 60 percent time in therapeutic range; correct?

23 A. Yes.

24 Q. So she actually had a better time in therapeutic range  
25 on warfarin than the patients that were used in the trial,

1 Pradaxa trial to compare warfarin; correct?

2 A. Correct, but it's not ideal.

3 Q. While Ms. Knight, or Betty was on warfarin do you agree  
4 with me that not one of her doctors put in the record that  
5 they recommended she needed to switch to a different  
6 anticoagulant medication?

7 A. Yes. However, I have a qualification to that.

8 Q. Okay.

9 A. The records are incomplete.

10 Q. Okay. You said you saw records from 2008 until the  
11 time Betty died?

12 A. You and I know there are many records in 2008 that are  
13 missing.

14 Q. Ma'am, you saw records from 2008 to 2009?

15 A. Yes.

16 Q. Okay. And in any of those records did you see any  
17 instance where any of her doctors, any of them, hospital,  
18 doctors who treated her at their office said, "We think  
19 Betty Knight needs to be on a drug different than warfarin  
20 to prevent strokes"?

21 A. Dr. MacFarland.

22 Q. When was that, ma'am?

23 A. When we showed you the switch to the NOAC.

24 Q. To Pradaxa?

25 A. Uh-huh.

1 Q. You're aware that that was actually initiated by Betty  
2 Knight's family; correct?

3 A. Not according to the note.

4 Q. Okay. Have you reviewed all the records?

5 A. Yes.

6 Q. Okay. Have you reviewed all the depositions?

7 A. Yes.

8 Q. Okay. And you saw the -- you reviewed the deposition  
9 of Rick Knight and Claudia Stevens; right?

10 A. Yes.

11 Q. Did you choose to disbelieve their testimony?

12 A. No, absolutely not.

13 Q. Okay. And you saw -- you read the deposition of  
14 Dr. MacFarland; correct?

15 A. Yes.

16 Q. And she said that the records reflected someone called  
17 from Betty Knight's family and requested that she be  
18 switched; correct?

19 A. Correct. But MacFarland wrote on an official piece of  
20 paper that goes into the insurance company the reasons for  
21 why the switch was made. So I have no doubts about the  
22 family contacting MacFarland, but it wasn't a unilateral  
23 decision.

24 Q. Understood. Prior to that, prior to that medical  
25 appointment that they had with Dr. MacFarland's office, did

1 you see any record where Dr. MacFarland wrote, "Betty Knight  
2 needs to switch to a different anticoagulant medication"?

3 A. No.

4 Q. You spent some time talking about November of 2008  
5 where you said that you thought the records reflected that  
6 Betty had a GI bleed on warfarin; is that right?

7 A. That is correct.

8 MR. CHILDERS: I apologize, Your Honor.

9 THE COURT: That's all right.

10 (Pause)

11 BY MR. CHILDERS:

12 Q. You reviewed those records and I think even walked  
13 through them some with Mr. Lewis; correct?

14 A. Correct.

15 MR. CHILDERS: May I approach, Your Honor?

16 THE COURT: You may.

17 BY MR. CHILDERS:

18 Q. Doctor, I've handed you the records from that November,  
19 2008 deposition. Do you see that?

20 A. Yes.

21 MR. CHILDERS: And for the record, Your Honor,  
22 this is out of Exhibit 2000 which has already been admitted  
23 into evidence and these are Pages 3178 through 3199.

24 BY MR. CHILDERS:

25 Q. Correct?

1 A. Correct.

2 Q. Nothing in these records says that Betty Knight noticed  
3 that she was having any red blood or bleeding that she  
4 noticed; correct?

5 A. There is a mention of dark stools.

6 Q. We'll get there. Is there any mention of a bleed in  
7 the history and physical?

8 A. No, not in -- not in the first page.

9 Q. And that tells you why the person came into -- I'm  
10 sorry. Could we -- the history and physical tells you why a  
11 person came into the hospital; right?

12 A. Yes.

13 Q. Chief complaint tells you this is why the person came  
14 to the hospital; right?

15 A. That is correct.

16 Q. And then underneath that we have the history of present  
17 illness which doesn't at all mention anything about GI  
18 bleed; correct?

19 A. Keep in mind -- no. Her hemoglobin at that time was  
20 10.

21 Q. Does it mention GI bleed?

22 A. Not there.

23 Q. Okay. And I thought you said earlier today that she  
24 went to the hospital complaining of symptoms consistent with  
25 a GI bleed; is that right?



1 A. Yes, weakness and mental status changes.

2 Q. Okay. She was also coming in because of problems with  
3 her heart; right?

4 A. Correct.

5 Q. Are weakness and mental status changes symptoms of  
6 that?

7 A. Yes, can be.

8 Q. Okay. If we would -- if you would turn the page with  
9 me to 3179, if we look -- if we blow up under the Review of  
10 Systems, do you see there's a section for GI in the Review  
11 of Systems?

12 A. Yes.

13 Q. And that says no melena, hematochezia, nausea, vomiting  
14 or diarrhea; correct?

15 A. That is correct.

16 Q. And that means -- well, let's start with melena.  
17 Melena means black stools; right?

18 A. It does.

19 Q. It says she didn't have black stools; right?

20 A. In there it does, yes.

21 Q. And then hematochezia, that's a bloody stool; right?

22 A. That is correct.

23 Q. And it says she doesn't have that; right?

24 A. In this note, yes.

25 Q. Okay. The lab at the hospital can actually -- if you

1 can't see blood, they can actually test someone's stool to  
2 see if there's microscopic blood in the stool; correct?

3 A. That's pretty archaic. We don't do that very routinely  
4 anymore.

5 Q. Can they do it or not?

6 A. You can do it.

7 Q. Okay. And it's called a guaiac test?

8 A. Yes, but the guaiac is positive for numerous reasons so  
9 we don't, we don't use it as gastroenterologists. It's  
10 extraordinary. The last time I ordered a guaiac was maybe  
11 four years ago.

12 Q. You realize this was more than four years ago; right?

13 A. Yes.

14 Q. Okay. This was 10 years ago; right?

15 A. Ten years ago.

16 Q. Yeah, November of 2008.

17 A. Time flies when you're having fun.

18 Q. So it wasn't such an ancient test back then; right?

19 A. Yeah.

20 Q. Okay. And there's no evidence in the record that they  
21 did -- that they found a positive guaiac from her stool;  
22 correct?

23 A. That is correct.

24 Q. Okay. If we could turn to Page 3181 which is a consult  
25 from Dr. Haberman, do you see that?

1 A. I do.

2 Q. He doesn't mention GI bleed anywhere in this record;  
3 correct?

4 A. That is correct.

5 Q. And he doesn't mention that he saw any evidence of a GI  
6 bleed; correct?

7 A. Let me see. That is correct.

8 Q. Okay. If we turn to the next page, there's a section  
9 called "Impression." Do you see that?

10 A. I do.

11 Q. And it says on the third one, "Anemia which might be  
12 secondary to the recent initiation of Coumadin." Do you see  
13 that?

14 A. I do see that.

15 Q. So this is the part where he's trying to decide what's  
16 causing the anemia; right?

17 A. Correct.

18 Q. And he says it might be related to the Coumadin;  
19 correct?

20 A. Yes.

21 Q. Okay. So this is the beginning of the investigation  
22 that he does; right?

23 A. Yes.

24 Q. Okay. And then -- and, by the way, the words "GI  
25 bleed" don't appear anywhere in that impression; correct?

1 A. Not in there, no.

2 Q. All right. The words "GI bleed" don't appear in any  
3 one of the pages out of the whole bunch that I gave to you,  
4 do they?

5 A. No, but why would you have a gastroenterologist  
6 involved?

7 Q. Is all you do is treat GI bleeds?

8 A. No. We treat other things.

9 Q. Okay. So it wouldn't be unusual for you to treat a  
10 patient who wasn't having a GI bleed; right?

11 A. As an in-patient, it's usually the majority of the time  
12 GI bleeding. It's not usually for reflux or something that  
13 can be managed as an out-patient, so the majority of the  
14 time.

15 Q. Okay. Did you see the words "GI bleed" anywhere in all  
16 these records?

17 A. No. Like I said, I saw dark stools and a hematocrit  
18 drop.

19 Q. I promise you we'll get there.

20 A. Okay.

21 Q. If we could turn two pages to Page 3184, do you see  
22 this is the following day?

23 A. I do.

24 Q. And this time she was seen by Dr. Rohrbach; correct?

25 A. Yes.

1 Q. Okay. And we heard -- I think you talked a little bit  
2 about this record earlier -- that he's a cardiologist; is  
3 that right?

4 A. That is correct. He's a gastroenterologist.

5 Q. Or a gastroenterologist. I apologize.

6 A. Yes.

7 Q. And then do you see anything in the ancient -- in the  
8 history that says she's noticed she's having blood coming  
9 from her rectum?

10 A. I don't know if I should repeat what he says again.  
11 But it says clearly that she has had diarrhea for about two  
12 days -- and mind you, you get diarrhea with GI bleeding --  
13 after the CT scan and said it was a little darker than  
14 usual.

15 Q. Was that CT scan with or without contrast?

16 A. I don't know.

17 Q. Okay. Would you expect a patient might have diarrhea  
18 after getting contrast dye from CT?

19 A. You can --

20 Q. Okay.

21 A. -- but not two days later.

22 Q. He, he timed it to the CT scan; correct?

23 A. He says for about two days after.

24 Q. Okay. Meaning for two days after she had that CT scan,  
25 she said she had diarrhea; right?

1 A. That is correct.

2 Q. And then he says, "And said it was a little darker than  
3 usual." Right?

4 A. That is correct.

5 Q. And that's what you're telling the jury is black  
6 stools; right?

7 A. Absolutely.

8 Q. Okay. Did he say anywhere in the record that he saw  
9 any black stools?

10 A. No, he doesn't.

11 Q. Did he say in the record anywhere that he had her  
12 stools tested and they were guaiac positive meaning there  
13 was blood in them?

14 A. No.

15 Q. Okay. And then if we look on the following page, we  
16 have a section called "Impression." Do you see that?

17 A. I do.

18 Q. And it says, "Anemia. This certainly does need  
19 evaluation given her need for long-term anticoagulation. We  
20 will start her work-up with an upper endoscopy. And if this  
21 is unremarkable, at some point she will probably require  
22 colonoscopy as well." Right?

23 A. That is correct.

24 Q. And you told us about endoscopies. You do them all the  
25 time.

1 A. Absolutely, yes.

2 Q. That's using a scope to go look into the person's GI  
3 tract?

4 A. Yes.

5 Q. If you turn to the next page, do you see this is the  
6 following day while she's still in the hospital?

7 A. My next page is a catheterization report.

8 Q. That's right. That's the next day while she's still in  
9 the hospital; correct?

10 A. Yes.

11 Q. Okay. And that catheterization report notes -- if we  
12 can click off of that, Gina, down to the very bottom and  
13 going on to the next page -- do you see it notes that during  
14 this catheterization she had stents placed?

15 A. That is correct.

16 Q. To have a procedure like this, Betty had to be off of  
17 her anticoagulant; correct?

18 A. Potentially, yes.

19 Q. That's standard practice. If you're going to do a  
20 stent, you're going to do a heart catheterization, you take  
21 the patient off their anticoagulant, don't you?

22 A. Yes.

23 Q. Okay. And then if we look at the following page, 3187,  
24 this is that same record. And the plan -- it says that the  
25 decision -- number six says the decision of whether to

1 restart the Coumadin will be left to Dr. Haberman; right?

2 A. Yes.

3 Q. So the cardiologist did a heart catheterization while  
4 she's not on, not on warfarin because that's standard  
5 procedure; right?

6 A. Correct.

7 Q. And they said whether or not she restarts it, that's  
8 somebody else's decision; right?

9 A. Correct, but she's been in the hospital now -- if you  
10 look at the date of procedure, she has been in the hospital  
11 for a few days by then. So --

12 Q. I understand that. My question simply was the doctors  
13 who did the heart catheterization said somebody else is  
14 going to decide whether or not she goes back on it; right?

15 A. Correct.

16 Q. And then if we turn one more page, we see the actual  
17 endoscopy report that Dr. Rohrbach said he wanted to  
18 perform; right?

19 A. Yes.

20 Q. And he did what's called an upper endoscopy meaning he  
21 checked from her throat or -- excuse me -- from her mouth, I  
22 guess, all the way into her stomach. Did he go past her  
23 stomach?

24 A. To the small bowel, the beginning portion of the small  
25 bowel which is, again, like I described before, just a



1 minority of the entire GI tract.

2 Q. When you do an endoscopy, you do upper or you do lower  
3 endoscopy; right?

4 A. Yes.

5 Q. This was the upper; right?

6 A. That is correct.

7 Q. Okay. And what he said right here, no blood was noted.  
8 Right?

9 A. In the upper tract, yes.

10 Q. Well, that's the only place he was checking; right?

11 A. Yes.

12 Q. The entirety of the area he checked, no blood was  
13 noted; right?

14 A. Correct.

15 Q. And then he wrote "normal upper endoscopy;" right?

16 A. He did.

17 Q. This record from the actual test that was done where  
18 the scope was put into Betty's body didn't show any evidence  
19 of a GI bleed; right?

20 A. Right. About -- again, as I want to point out, it's  
21 less than five percent of the GI tract. So there was about  
22 95 percent of the GI tract that's uncovered here.

23 Q. Okay. And in looking at that part of the GI tract,  
24 there's not any evidence of a GI bleed; correct?

25 A. That is correct.

1 Q. You testified several times now Betty had dark stools;  
2 right? That was what you thought it meant when it said  
3 diarrhea that was a little darker than usual?

4 A. Yes.

5 Q. Do you agree with me dark stools are more likely to be  
6 from an upper GI bleed than from a lower GI bleed?

7 A. That is correct.

8 Q. Okay. And, again, Betty's endoscopy showed no upper GI  
9 bleed; correct?

10 A. No, but I have a qualification there.

11 Q. My question was really a "yes" or "no."

12 A. Okay.

13 Q. And then if we look to the following page, Betty was  
14 discharged the following day; right?

15 A. She was.

16 Q. And then if we look below that, there's a list of 24  
17 discharge diagnoses; right?

18 A. Yes.

19 Q. Not one of those says gastrointestinal bleed, does it?

20 A. Iron deficiency, anemia.

21 Q. Do you see the words "gastrointestinal bleed" anywhere,  
22 Doctor?

23 A. No.

24 Q. All right. You showed us a progress note from Dr.  
25 Gunnalaugsson. You talked about that with Mr. Lewis. I

1 believe it was Exhibit 9009-0273. And this was from, about  
2 a month, less than a month later, December 5th, 2008;  
3 correct?

4 A. I see it.

5 Q. And I think if you still have the binder that Mr. Lewis  
6 gave you, it's in there under that number, tab 9009-A, page  
7 number 273. I wrote this down when you were testifying, so  
8 I apologize if I got it wrong. But I thought what I heard  
9 you say was this one progress note meant to you that all of  
10 Betty Knight's healthcare providers were in agreement that  
11 Betty had a GI bleed. Is that what you said?

12 A. So there are numerous references to her chronic GI  
13 bleeding. MacFarland has mentioned it in prior notes. Her  
14 cardiologist has mentioned it in prior notes. So it's not  
15 all of them, but it's more than one.

16 Q. So -- but that was based on this record that you told  
17 us you thought this meant to you her doctors, whether they  
18 be all or some, were in agreement that she had a GI bleed;  
19 right?

20 A. Yes.

21 Q. And that GI bleed you're talking about is the one that  
22 we just saw was not actually written as a GI bleed anywhere  
23 in the records we looked at; right?

24 A. It wasn't written in the records, correct.

25 Q. Okay. You relied on more than just this one record

1 from Dr. Gunnalaugsson; correct?

2 A. Yes.

3 Q. There was another office visit that you looked at with  
4 Mr. Lewis from Dr. Gunnalaugsson that was from a few months  
5 after this?

6 A. Correct.

7 Q. March 12th, 2009?

8 A. Uh-huh.

9 Q. And that was Exhibit Number 9005-26. Do you recall  
10 seeing that?

11 A. I do.

12 Q. My recollection was you guys talked about the second  
13 page but didn't talk about the first page of this document.  
14 Is that right?

15 A. Correct.

16 Q. Let's look at the first page with the jury. Okay?

17 And if you could blow that back up, Gina.

18 I'm sorry, wrong page. I'm sorry, past medical history  
19 on Page 1.

20 Number four says "history of presumed GI bleed although  
21 not confirmed." Correct?

22 A. It says it on there, but that's different than what he  
23 said in other notes.

24 Q. This is after the note that we just looked at that you  
25 said was -- told you all of her doctors were in agreement

1 that she had a GI bleed; correct?

2 A. She did have a GI bleed, correct.

3 Q. This record is made by the same doctor who previously  
4 said he thought she had a GI bleed; correct?

5 A. Correct.

6 Q. And this was three months after the record that we have  
7 looked at before; right?

8 A. Can I --

9 Q. Is it three months after or is it not three months  
10 after?

11 A. It is. But can I interject something important?

12 Q. You can when your counsel gets back up and asks some  
13 more questions.

14 A. Okay. Fair enough.

15 Q. Sorry. We have certain rules.

16 A. Fair enough.

17 Q. I think you also testified, if I heard you correctly,  
18 Ms. Knight had never been on Plavix, aspirin, and Coumadin  
19 at the same time; right?

20 A. Not the records that I've seen, that I've been  
21 provided.

22 Q. Let's just look at the record we're on right now.

23 A. Sure.

24 Q. What's listed under "Medications"?

25 A. Plavix, aspirin.

1 Q. Okay. If we go onto the next page of the same record,  
2 Coumadin?

3 A. Coumadin as directed.

4 Q. Right, meaning whatever dose you're supposed to be  
5 taking; right?

6 A. Correct.

7 Q. So when you told the jury she'd never been on those  
8 three medications together, that's wrong based on this  
9 record; correct?

10 A. She's been on and off the Coumadin. She's been on and  
11 off the aspirin. And, like I said, the records are pretty  
12 incomplete when it comes to Coumadin.

13 Q. This record is pretty clear. On the medications that  
14 she's on that day, Plavix, aspirin and Coumadin; correct?

15 A. I see that, yes.

16 Q. Okay. So when you told the jury she'd never been on  
17 all three of those medications before, you meant other than  
18 this record; right?

19 A. Well, I didn't notice this.

20 Q. This is a record --

21 A. My apologies to the jury.

22 Q. You talked about this record with counsel in your  
23 direct examination; right?

24 A. I did. I did.

25 Q. She didn't have a bleed while she was on those three

1 medications together, did she, Plavix, aspirin and Coumadin?

2 A. Not, not at this time. You're correct.

3 Q. She never did when she was on those three medications;  
4 correct?

5 A. That is correct.

6 Q. Okay, all right. I want to ask you some more about Dr.  
7 Gunnalaugsson.

8 A. Sure.

9 Q. You didn't only rely on his records. You relied on his  
10 testimony too. Correct?

11 A. Yes.

12 Q. Okay. And you agree with me that when you read his  
13 testimony, he said he was never able to confirm that she  
14 actually had a bleed, that Betty actually a GI bleed in  
15 November of 2008; correct?

16 A. That's correct.

17 Q. In fact, he said he didn't even look at the records  
18 that you and I just looked at together, didn't he?

19 A. I would have to re-read it.

20 Q. I'll show you in your own deposition, if you'd turn  
21 please to Page 115.

22 A. 115, sir?

23 Q. Yes.

24 MR. LEWIS: Your Honor, I object to the use of the  
25 deposition. She hasn't said anything inconsistent.

1 THE COURT: Well, --

2 MR. CHILDERS: May I refresh her recollection?

3 THE COURT: Yes, you may.

4 BY MR. CHILDERS:

5 Q. If you could just look --

6 MR. CHILDERS: Sorry, Your Honor. I went the  
7 wrong way with that one.

8 BY MR. CHILDERS:

9 Q. If you would look at Page 115, lines 22 through Page  
10 116, line 7, do you see that?

11 A. I do see that.

12 Q. Does that refresh your recollection that Dr.  
13 Gunnalaugsson said he never actually reviewed the records  
14 you and I just looked at with the jury?

15 A. Yes.

16 Q. Thank you.

17 A. That was nine months ago.

18 Q. I understand. So in Dr. Gunnalaugsson's records he  
19 says, "I never could confirm the bleed." And then in his  
20 deposition said, "I never confirmed a bleed." Right?

21 A. Correct, but he says it numerous times in the notes.

22 Q. I want to ask you about another hospital record that I  
23 don't think you talked about on your direct exam. It's  
24 already in evidence.

25 MR. CHILDERS: May I approach, Your Honor?



1 THE COURT: You may.

2 BY MR. CHILDERS:

3 Q. Do you see this as a consultation from February 10th,  
4 2009?

5 A. I see it.

6 Q. Do you recall reading this?

7 A. I do.

8 Q. Okay. And if we could look on this particular document  
9 under the history of present illness about halfway down  
10 starting -- do you see where it says, "Patient has been on  
11 Coumadin in the past. However, it was held because of the  
12 percutaneous coronary intervention and was not restarted."  
13 Do you see that?

14 A. Correct.

15 Q. The percutaneous coronary intervention is the stent  
16 procedure that we just talked about as well; right?

17 A. That is correct.

18 Q. And that is a procedure in which it is standard  
19 practice to stop taking an anticoagulant before you perform  
20 it; correct?

21 A. Correct, to stop it with a qualification.

22 Q. Any anticoagulant, no matter what you're on, has to be  
23 stopped before you have a procedure like that; right?

24 A. Correct.

25 Q. Okay. This document -- and feel free to look at all

1 five pages -- doesn't say that Betty had a bleed while she  
2 was on Coumadin; correct?

3 A. Correct.

4 Q. Okay. Now, this is during a hospitalization that we --  
5 you talked some about with Mr. Lewis where they found that  
6 she actually had a clot in her arm?

7 A. Correct.

8 Q. Betty had a clot in her arm. I want to ask you a  
9 little bit further about that. She wasn't on Coumadin at  
10 the time; correct?

11 A. Correct.

12 Q. Even though she wasn't on Coumadin, Betty had anemia  
13 during that hospitalization again; right?

14 A. She did.

15 Q. She hadn't been on Coumadin for three months at that  
16 point?

17 A. That is correct.

18 Q. All right. I want to talk to you about the records  
19 from that particular hospitalization.

20 Actually, I apologize. You already have them in front  
21 of you, that same document that I already gave you.

22 The next page, if you'll turn over, do you see that,  
23 3219? That is a consult from three days after the record we  
24 just looked at, four days, excuse me. Sorry. Three days  
25 after; right?

1 A. Yes.

2 Q. Same hospitalization; right?

3 A. Correct.

4 Q. And the very first sentence under History of Present  
5 Illness says, "The patient is a 79-year-old white female  
6 seen in consultation at the request of Dr. MacFarland for  
7 evaluation of anemia." Right?

8 A. That is correct.

9 Q. And, again, it says further down that although she says  
10 she had some dark stools at home prior to admission, she  
11 denies any frank melanotic --" it should say "stools" but it  
12 says "schools" -- or hematochezia." Right?

13 A. That is correct.

14 Q. Again, that means she's not seeing any dark stools or  
15 bloody stools?

16 A. Not -- that's not quite correct.

17 Q. Well, what does it say when it says denies frank  
18 melanotic stools?

19 A. She has had some dark stools at home prior to  
20 admission. The patient says that she has had some dark  
21 stools prior to admission. I'm assuming that's Betty  
22 Knight.

23 Q. Okay. And, again, she's not on Coumadin at that time;  
24 right?

25 A. She is not on Coumadin.

1 Q. She's not on any anticoagulant; right?

2 A. No.

3 Q. Okay. And if we look --

4 A. She is on aspirin, an anti-platelet agent but she's not  
5 on Coumadin.

6 Q. If we turn to the next page, Gina, under "Diagnostic  
7 Data," do you see that?

8 A. Can I -- so she's on Plavix and aspirin at this point.

9 Q. Understood. She's not on warfarin; right?

10 A. I just want to make that clear.

11 Q. Sure. She's not on Coumadin; right?

12 A. She's not on Coumadin, correct.

13 Q. And it says her hemoglobin on February 7th was 12.1.  
14 It has dropped to 9.1. She has received two units of packed  
15 red blood cells. Correct?

16 A. That's correct.

17 Q. That's almost identical to the same blood drop that she  
18 had in the November, 2008, hospitalization; right?

19 A. Absolutely.

20 Q. When she was on Coumadin; correct?

21 A. Correct.

22 Q. Just like the November of 2008 hospitalization, there's  
23 no mention in the records from this hospitalization that --  
24 of a diagnosis of GI bleed; right?

25 A. That is correct.

1 Q. You testified earlier today that -- and, again, I'm  
2 sorry if I -- I may be paraphrasing. I think you said the  
3 warfarin just didn't work for her, meaning Betty Knight. Is  
4 that what you said?

5 A. It was very difficult for Betty Knight to stay  
6 therapeutic.

7 Q. Well, that's not what -- I'm sorry. Go ahead.

8 A. No. That's what I said.

9 Q. What you said was it didn't work for her; correct?

10 A. Correct.

11 Q. And when you say it didn't work for her, you mean it  
12 didn't prevent strokes or it caused bleeds. That's what  
13 Coumadin is made to do, right, to prevent strokes and  
14 hopefully not cause you to bleed.

15 A. Right. But it's not going to work for you if you can't  
16 stay therapeutic.

17 Q. And I think you said there were challenges keeping  
18 Betty's INR in the therapeutic range.

19 A. Absolutely.

20 Q. Despite those challenges, you agree that none of those  
21 challenges caused Betty Knight to have a stroke?

22 A. She did not have a stroke during the time she was on  
23 Coumadin.

24 Q. She didn't have a clot of any kind; correct?

25 A. That is correct. That -- from the records that we have

1 which, again, are very shoddy at this time, that is correct.

2 Q. They're what you base your opinions on, correct, the  
3 records?

4 A. Correct.

5 Q. And in all the records you looked at, Betty Knight did  
6 not suffer a stroke while she was on Coumadin; correct?

7 A. That is correct.

8 Q. There's not even a mention that Betty Knight had a  
9 stroke while on Coumadin; correct?

10 A. Correct.

11 Q. In all the records you reviewed, none of the INR  
12 challenges that Betty had caused her to suffer a bleed;  
13 correct?

14 A. She, like I said, had a bleed in November of 2008.

15 Q. Okay. We've talked about that. I'm talking about her  
16 INR fluctuations that you called challenges. Okay?

17 A. Okay.

18 Q. You agree with me none of those fluctuations or  
19 challenges led to Betty Knight having a bleed; right?

20 A. Correct.

21 Q. Okay. So as far as preventing stroke, Coumadin worked  
22 for Betty Knight; right?

23 A. On the time she was on it, absolutely.

24 Q. And as far as -- well, sorry. I'm looking at my paper  
25 while I'm trying to talk. I think we're ready to move on to

1 topic two and you tell me if I get this right.

2 Topic two that you were asked about was: What was the  
3 cause of Betty's GI bleed? Did I get that right? Was that  
4 the second thing that you were supposed to talk with him  
5 about?

6 A. That's fine. That's one of them.

7 Q. We already talked about the fact that you don't  
8 actually have any opinion that any of the medications she  
9 was on caused that bleed; right?

10 A. Right. We can't say which one did, which one didn't.  
11 That is correct.

12 Q. You're not giving any opinion that any one of them  
13 played any part in her bleed; correct?

14 A. I have not.

15 Q. And you're not ever going to; correct?

16 A. Ever going to?

17 Q. In this case.

18 A. That's a pretty -- yes.

19 Q. Mr. Lewis isn't going to get back up and all of a  
20 sudden you're going to say, "You know what. I changed my  
21 mind. These did play a part." You're not going to do that;  
22 right?

23 A. Correct.

24 Q. The reduction of bleed risk in patients is a high  
25 priority of your medical care, isn't it?

1 A. Yes.

2 Q. Okay. And you agree with me that patients who are on  
3 Pradaxa have a higher risk of GI bleed than patients who are  
4 on warfarin; right?

5 A. Correct, with a qualification.

6 Q. In the clinical trials that were done on Pradaxa in  
7 AFib patients, the risk of GI bleed was 50 percent higher if  
8 you were on Pradaxa than if you were on warfarin; right?

9 A. Correct. But they had a lower incidence of brain  
10 bleeds as well as strokes.

11 Q. You don't treat brain bleeds, do you, Doctor?

12 A. Not directly, correct.

13 Q. You don't treat strokes, do you, Doctor?

14 A. No, but I'm concerned about my patients getting those.

15 Q. You treat GI bleeds; right?

16 A. I do.

17 Q. And that's why you're here?

18 A. I am.

19 Q. Okay. And, so, when we're talking about GI bleeds, you  
20 agree with me that patients on Pradaxa are 50 percent more  
21 likely to have a GI bleed than a patient who's on warfarin;  
22 right?

23 A. That's correct.

24 Q. If I understand correctly, you have no idea why that  
25 is. You don't know why patients who are on Pradaxa have



1 50 percent more GI bleeds than on warfarin; right?

2 A. That is correct.

3 Q. I want to show you an exhibit and ask if you've ever  
4 seen it. This is Exhibit 138.

5 MR. CHILDERS: May I approach, Your Honor?

6 THE COURT: You may.

7 THE WITNESS: Thank you.

8 MR. CHILDERS: This is already admitted into  
9 evidence, Your Honor, Exhibit 138.

10 THE COURT: All right.

11 BY MR. CHILDERS:

12 Q. Doctor, have you been provided this document by counsel  
13 for Boehringer?

14 A. It doesn't look familiar.

15 Q. Do you see --

16 A. But I've had a lot of records to review.

17 Q. This is an email chain. Do you see that?

18 A. I do.

19 Q. And the folks who are on this email chain are Dr.  
20 Clemens, Dr. Heinrich-Nois, and Dr. Van Ryn. Do you see  
21 that?

22 A. I do.

23 Q. Are you aware they all work for Boehringer Ingelheim?

24 A. Yes.

25 MR. LEWIS: May we approach, Your Honor?

1 THE COURT: Yes, you may.

2 (Bench conference on the record)

3 MR. LEWIS: This is a document, Your Honor, that  
4 this witness has no foundation to testify about. It wasn't  
5 in her reliance materials. In fact, she didn't testify  
6 about any company documents whatsoever. It's not even  
7 relevant to her testimony. It's clearly outside the scope  
8 of my direct.

9 THE COURT: What do you intend to elicit?

10 MR. CHILDERS: This is a document from the company  
11 that says we think we know why people have a higher rate of  
12 GI bleeds on Pradaxa than warfarin. And my point is she's  
13 testified she knows that's the case. She doesn't know why.  
14 And they haven't shared this information with her even  
15 though they hired her as an expert in the case.

16 MR. LEWIS: But I didn't even ask her about -- I  
17 didn't even cover it with her. It's not even part of her  
18 opinion. She's an expert that came in to assess the  
19 specific circumstances of Mrs. Knight, not the general -- I  
20 didn't ask her any general testimony about what is the cause  
21 of GI bleeding generally in Pradaxa. In fact, I was cut off  
22 from that. I was specifically not permitted to ask her  
23 generally about whether Pradaxa was safe and effective. I  
24 was precluded from this very topic.

25 MR. CHILDERS: I don't think that's the case.

1 THE COURT: I think it was. It's awful close to  
2 that.

3 MR. CHILDERS: The question he was not allowed to  
4 ask was, was it safe and effective for Betty Knight. That's  
5 not my question to her. My questions relate to does she  
6 know why there's this higher incidence of GI bleeds or not.

7 If she says "no" -- I'm showing her documents from the  
8 company that seem to explain why that is to see if she knows  
9 that or not. It's the company she's working for as an  
10 expert.

11 MR. LEWIS: I didn't cover any of this with her.  
12 I didn't cover the reasoning behind the operation of the  
13 medication and why there would be an increase of a GI bleed.  
14 I didn't cover any of this with her. It wasn't even in her  
15 opinions. I was precluded from asking about safety and  
16 efficacy of Pradaxa for this patient.

17 MR. CHILDERS: Her opinion is nobody can say she  
18 wouldn't have had the same bleed on another medication.  
19 This is evidence that she's more likely to have the bleed on  
20 Pradaxa than warfarin. And so it goes directly to that  
21 opinion and it's from the company itself and it's already  
22 into evidence, Your Honor. That is clearly one of her  
23 opinions.

24 THE COURT: Who did this come from?

25 MR. CHILDERS: Dr. Van Ryn's deposition.

1 MR. LEWIS: She wasn't asked about the company  
2 bases for her position on what the medication -- the  
3 complication profile of the medication. She wasn't asked  
4 about those general things during her direct.

5 MR. CHILDERS: She was asked -- she said my  
6 opinion is you can't say she wouldn't have had this bleed on  
7 Pradaxa -- on warfarin versus Pradaxa. This is evidence to  
8 support that you can say that and here's why because we know  
9 why you have a higher risk of GI bleed on Pradaxa than you  
10 do on warfarin. I think it goes directly to her opinion.

11 THE COURT: I'm going to allow it. It's  
12 cross-examination.

13 MS. JONES: May I make one other point? If this  
14 has already been run through Dr. Van Ryn, then it's  
15 cumulative of evidence the jury has already heard. If our  
16 experts are suddenly going to become a factor for them to  
17 rewrite company documents, this is going to be a longer  
18 trial than we anticipated.

19 THE COURT: It's cross-examination of your expert.  
20 I'll allow it.

21 (Bench conference concluded)

22 THE COURT: Go ahead.

23 MR. CHILDERS: Thank you, Your Honor.

24 BY MR. CHILDERS:

25 Q. Doctor, did you have a chance to review this while we

1 were up there chatting with each other?

2 A. I didn't know if I should or not to be honest so --

3 Q. Fair enough. Do you see again this is an email that is  
4 being exchanged among employees at Boehringer Ingelheim;  
5 correct?

6 A. I do.

7 Q. And this was back all the way in 2009; right?

8 A. Okay.

9 Q. Do you see that?

10 A. I do.

11 Q. Okay. And the subject is "thrombin effects for  
12 mucosa." Do you see that?

13 A. I do.

14 Q. And when you read the -- if you would read the email,  
15 if you need a minute to do it, I want you to look at it and  
16 see if you agree with me that what they're trying to figure  
17 out is why are we having more GI bleeds on Pradaxa than on  
18 warfarin. Do you see that? Do you agree with me that's  
19 what they're talking about?

20 A. It appears that this email you gave me talks about  
21 that, yes.

22 Q. Okay. And it started with Dr. Heinrich-Nois sending an  
23 email to Dr. Van Ryn saying, "I'm trying to figure out  
24 what's going on here. What is this happening?" Right.

25 A. I guess so. Again, I have no context here. I'm just

1 given an email with the two different -- I've got two  
2 different emails. I have no idea what the context is.

3 Q. Okay. Let me read it to you and see if you agree that  
4 I read it correctly. Okay?

5 It says, "Dear Joanne, I'm still struggling with the  
6 increased gastrointestinal bleed rate under dabigatran."

7 Do you see that?

8 A. I do.

9 Q. That's Pradaxa; right? Dabigatran?

10 A. Yes.

11 Q. All right. And then although she says there's no  
12 obvious explanation, she goes on to say, "So I wonder  
13 whether thrombin is known to play any role or contributes to  
14 the composition of gastric mucous."

15 Do you see that?

16 A. I do.

17 Q. Okay. And then Dr. Van Ryn responds to her the next  
18 day. Do you see?

19 A. I do.

20 Q. Okay. And I want to go to the very last paragraph of  
21 her response and look at that with you.

22 And do you see she says, "Last point about GI bleeds  
23 and this is something you should get Sebastian Haertter to  
24 look at closely. I think that the 95 percent of dabigatran  
25 that does not get absorbed but remains in the gut is also

1 converted into dabigatran by --"

2 Can you -- do you know what that word is? It looks  
3 like a medical word.

4 A. Esterases. They're enzymes.

5 Q. And they're in the GI tract?

6 A. Yes.

7 Q. Okay. And then she goes on to say, "I have talked to  
8 several people, Joachim, Sebastian, and Astrid Volz," who  
9 she notes is a P-gp specialist. Right? Do you see that?

10 A. I see that.

11 Q. And then she says, "and have received different answers  
12 from all of them to, no, this does not happen to, yes, it is  
13 completely converted to maybe partially converted."

14 And then she goes on to say, "If you have active  
15 substance in the gut and slight GI injury somewhere, then  
16 you have increased bleeding risks. At least biologically  
17 for me it would be an obvious explanation."

18 Do you see that?

19 A. I see that.

20 Q. Okay. That was in 2009; right?

21 A. An email in 2009, correct.

22 Q. An internal company email in 2009; right?

23 A. Correct.

24 Q. Okay. The next thing I want to show you --

25 THE COURT: We need to take a break at a

1 convenient point. Is now good or --

2 MR. CHILDERS: That would be fine, Your Honor.

3 THE COURT: All right. We're going to take a  
4 brief recess. You may retire to the jury room.

5 (Recess taken at 3:23 p.m.)  
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1 (Back on the record at 3:30 p.m.)

2 (Jury not present.)

3 THE COURT: Before we get back into this, I will just  
4 tell you my clerk is assembling two copies for each side of  
5 the Court's last draft of proposed final instructions. So as  
6 soon as he has got them out here, he is going to bring two  
7 copies and lay them on your desk.

8 At this point, my guess is we're going to have to take  
9 these up after the jury goes home this evening, so be prepared  
10 to stick around awhile to do that.

11 With that, let's go back to this issue, then. Where  
12 are we?

13 MR. CHILDERS: With the exhibit, Your Honor?

14 THE COURT: Yes.

15 MR. CHILDERS: So it does appear, and I apologize,  
16 it's from Dr. Van Ryn's deposition, but it was not played.  
17 That's my fault, I thought it had been played. We've cut  
18 these depositions up quite a bit.

19 But, regardless, Dr. Shami listed in her materials  
20 reviewed transcripts and associated exhibits from depositions  
21 taken in the Pradaxa litigation in the federal MDL Connecticut  
22 state court proceedings. That's where Dr. Van Ryn's testimony  
23 was taken. So she's relied on that material, or at least  
24 purports to have relied on it in her report. So it's an  
25 admission of a party opponent that we believe would come in as

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1 something she relied on.

2 MR. LEWIS: The problem, Your Honor, is that the  
3 proper foundation wasn't laid with this witness to talk about  
4 that document. It's not in her reliance materials. She  
5 hasn't even seen it before. Maybe she reviewed some  
6 depositions here and there, but it's definitely a real problem  
7 that it was represented that it was admitted into evidence.

8 The basis of that was, I think, used by the Court to  
9 rule that she could be cross-examined on it. That deposition  
10 has not been played to the jury, that issue hasn't come up in  
11 Dr. Van Ryn's deposition, and I've got a real problem -- one,  
12 it's not admissible independently without a foundation.  
13 Number two, we need to fix what just happened here because  
14 that's a serious issue what they just got into in front of the  
15 jury.

16 THE COURT: Anything else?

17 MR. CHILDERS: I disagree, Your Honor. I think if she  
18 says she relied on the transcripts and exhibits from that  
19 deposition, it's the entirety of it, not just what was played  
20 in court. And, I mean, she didn't break it all out by  
21 witness, but she says transcripts, and it was an admission.

22 THE COURT: Well, I don't think that's enough.

23 The witness, first, clearly responded that she didn't  
24 recall the document, didn't testify that she had seen it.  
25 When you folks assemble these huge files and provide it to

1 each other or witnesses or experts, I think you bear the risk  
2 of determining specifically, and in particular the case of  
3 experts, what specifically they are relying upon in reaching  
4 their opinions. I think that I've applied the reverse of that  
5 and precluded testimony about things where the witness didn't  
6 indicate that, as an expert, he or she relied upon something  
7 specific.

8 Here, I accept it as good faith, and I'm sure it was  
9 meant that way, counsel's representation that it was already  
10 admitted as an exhibit in Dr. Van Ryn's testimony. Assuming  
11 that to be the case, my finding was that you could examine her  
12 about it.

13 I premised that conclusion based on, first,  
14 determining that in the course of her direct testimony, she  
15 testified extensively about what she characterized as the  
16 difficulties or challenges presented by having Betty Knight on  
17 warfarin and why both explicitly and implicitly it was good  
18 for Betty Knight to change to Pradaxa. And so I believed that  
19 it would be fair to cross-examine her on an admitted statement  
20 against interest or statement by a party that provided an  
21 answer to a question that she said she didn't know and hadn't  
22 been provided.

23 She was testifying essentially that she didn't know  
24 what the -- what caused the Pradaxa bleed rates to be so much  
25 higher. If there was a company document which she had --

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1 which was admitted, which she had testified she was aware of  
2 that supplied that information, I think it would be fair to  
3 cross-examine her on it. I think it would be consistent with  
4 my ruling even limiting the direct examination as I did when  
5 Mr. Lewis first started.

6 But she can't authenticate this document. She  
7 testified she hadn't seen it, so she clearly has formed no  
8 opinion about it. I think it's inappropriate for her to be  
9 examined about the document.

10 My inclination is to simply inform the jury that I'm  
11 sustaining an objection by the defendant, finding that the  
12 witness has not admitted that she was aware of this document  
13 and that, therefore, any questions based upon this document  
14 about what BI knew or suspected was the reason for GI bleeds  
15 to be higher with Pradaxa is simply inadmissible.

16 MR. CHILDERS: Your Honor, I'm sorry. There's a  
17 ruling that she couldn't authenticate it?

18 THE COURT: That's part of it.

19 MR. CHILDERS: Okay. Because we have a stipulation  
20 that if it's a Boehringer-created document with a Bates number  
21 on it, it's deemed authenticated. And that's in the pretrial  
22 order, Your Honor.

23 MR. LEWIS: But it's not just about authenticity.  
24 It's the entire foundation. It doesn't end with just  
25 authenticity. It's the foundation for the testimony.

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1 In other words, does this witness know enough about  
2 this particular thing that is being admitted to be able to say  
3 it is and should be admitted.

4 THE COURT: Well, and literally I understood from  
5 counsel -- clearly this is what you said -- that it was an  
6 already admitted document. So --

7 MR. CHILDERS: That was incorrect, Your Honor.

8 THE COURT: I understand that. So based upon that,  
9 I'm going to grant the objection.

10 MR. LEWIS: Your Honor, may I be heard on the nature  
11 of the instruction that you're going to give to the jury?

12 THE COURT: Sure.

13 MR. LEWIS: I'm a little bit concerned by the way the  
14 Court -- sorry. I'm a little bit concerned by the way -- and  
15 I know Your Honor was just kind of talking through it, but the  
16 way the Court described about how this witness hadn't seen the  
17 document before.

18 And so I prefer a more generic statement, if I may,  
19 Your Honor, that the testimony about that document -- the  
20 objection is sustained, and the testimony about that document  
21 should be not considered or --

22 THE COURT: Well, I can do it simply enough by saying  
23 that upon a close review of the record, we now realize that  
24 this document had not been admitted into evidence. We thought  
25 that it had. Since it hasn't been admitted into evidence, I'm

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1 sustaining the objection to the question and ordering the jury  
2 to disregard her testimony as to that.

3 MR. CHILDERS: Understood, Your Honor. Thank you.

4 MR. LEWIS: Thank you.

5 THE COURT: All right. Let's bring the jury out.

6 (Jury present.)

7 THE COURT: All right. You may be seated.

8 All right. Ladies and Gentlemen, let's back up a  
9 little bit.

10 First, Mr. Childers was asking the witness a question  
11 about matters contained in an e-mail that he presented to her.  
12 Mr. Childers had a good faith belief at the time, as he  
13 represented to the Court and the defendant, that that e-mail  
14 was part of an exhibit that had already been admitted into  
15 evidence when Dr. Van Ryn testified by deposition last week.

16 Upon closer inspection, we find that is not the case.  
17 That document had not been admitted in her testimony.  
18 Therefore, I've sustained the objection by the defendant to  
19 the question and direct that you disregard any of the  
20 questions or responses that were made by the witness  
21 pertaining to that e-mail and what it said.

22 With that, you may resume the rest of your  
23 cross-examination.

24 MR. CHILDERS: Thank you, Your Honor.

25 Doctor, I want to show you an exhibit that you -- I'm

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1       sorry -- an article that you listed as something you relied on  
2       in this case.

3               Okay?

4               THE WITNESS:   Okay.

5               MR. CHILDERS:   May I approach, Your Honor?

6               THE COURT:    Yes, you may.

7       BY MR. CHILDERS:

8       Q.   You recognize this article, right?

9       A.   I do.

10      Q.   In fact, it's an article that you relied on for your  
11      opinions in this case?

12      A.   Yes.

13      Q.   Okay.   Could you tell the jury who the first named author  
14      is of this article?

15      A.   Eikelboom, E-I-K-E-L-B-O-O-M.

16      Q.   And you recognize Dr. Eikelboom as being one of the  
17      authors who -- excuse me -- one of the scientists who worked  
18      on the Pradaxa clinical trials, right?

19      A.   That is correct.

20      Q.   And he's published other articles about Pradaxa, correct?

21      A.   He has published, yes.

22      Q.   Okay.

23              MR. CHILDERS:   Your Honor, may I publish to the jury  
24      the article?

25              THE COURT:    You may.

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1 MR. CHILDERS: If we could look first on page 4.

2 Q. There's a section called Site of Major Gastrointestinal  
3 Bleeding, correct?

4 A. I see that.

5 Q. And this particular section is, you'll recall from when  
6 you read it before, Dr. Eikelboom and the other authors  
7 talking about where they saw in the gastrointestinal tract  
8 bleeding whether the patient was on Pradaxa or on warfarin,  
9 right?

10 A. Correct.

11 Q. Okay. And what they said was patients who had  
12 gastrointestinal bleeds who were taking Pradaxa, that it was  
13 about 50/50, right, 53 to 47 percent upper versus lower  
14 gastrointestinal tract, right?

15 A. That is correct.

16 Q. And then when they looked at the warfarin patients, that  
17 percentage was different, correct?

18 A. It says 75/25.

19 Q. Right.

20 So it was more likely for warfarin that you were going to  
21 have a bleed in the upper GI than the lower GI, at least  
22 according to the data that they collected in this trial,  
23 right?

24 A. Yes. In this one trial, correct.

25 Q. Okay. And this trial is the big trial that we've all



1 heard about that had 18,000 patients, right?

2 A. Yes.

3 Q. And I think we heard it was the largest clinical trial for  
4 an anticoagulant ever performed up to that point, right?

5 A. Correct.

6 Q. Okay. And so what they saw was, in the patients who had  
7 this GI bleeding, if it was in -- excuse me -- if they were on  
8 warfarin, it was more likely to be in the upper GI, right?

9 A. Correct. On this, yes.

10 Q. And then if we could turn, please, to page 8.

11 Do you see this is the section where they're talking  
12 about -- what's called a discussion, and they're talking about  
13 why they think this might be happening, right?

14 A. Yes.

15 Q. Okay. And they say: Blood level itself can't explain why  
16 we're seeing more GI bleeding or gastrointestinal bleeding in  
17 the lower GI tract with Pradaxa than we are with warfarin,  
18 right?

19 A. That's what they're discussing. They're trying to figure  
20 out why that is.

21 Q. Okay. And then a little further down, it says:  
22 Dabigatran has a low bioavailability after oral ingestion,  
23 right?

24 A. I'm sorry. Where are you?

25 Q. The next sentence: Dabigatran has a low bioavailability

1 after oral ingestion.

2 Do you see that?

3 A. I do.

4 Q. And then it says -- and what that means and what the jury  
5 has heard is when you take a pill of Pradaxa, only a little  
6 bit of it actually gets into your system as medicine, right?

7 Right?

8 A. Okay. Yes.

9 Q. You know that to be --

10 A. That's correct.

11 Q. Okay. And the rest of the medicine travels through the GI  
12 tract before it leaves the body, right, the inactive part of  
13 the medicine or the part that is not getting into your  
14 bloodstream, right?

15 A. Correct.

16 Q. Okay. And so what they're saying is -- I'm sorry.

17 What they go on to say is: It's possible that metabolism  
18 of dabigatran etexilate, which is the Pradaxa, by esterases,  
19 which we saw before, leads to progressively higher  
20 concentrations of the active drug during transit of the  
21 gastrointestinal tract.

22 That's what they said, right?

23 A. Right. Again, they're trying to hypothesize or come up  
24 with a reason.

25 Q. And the reason that they're hypothesizing is as this drug

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1 that didn't get into the bloodstream is going through the GI  
2 tract, it's actually having -- it's metabolizing in there and  
3 causing anticoagulant effect inside the GI tract, right?

4 A. This is a complete guesstimate on their part.

5 Q. Understood.

6 That's what they are hypothesizing may be the issue,  
7 right?

8 A. Yes.

9 Q. And you knew that when you read this article and relied on  
10 it, correct?

11 A. I mean, I relied on it for parts of the article, correct.

12 Q. Okay. And then if we look over to the next column, they  
13 say: Thus, local effects of dabigatran on diseased mucosa  
14 could account for the relative increase in lower  
15 gastrointestinal bleeding seen with dabigatran compared with  
16 warfarin in elderly patients in the RE-LY trial, right?

17 A. Correct. Again, another guesstimate.

18 Q. Sure.

19 And when they say local effects of dabigatran, they're  
20 talking about Pradaxa, right?

21 A. Yes, they are.

22 Q. And when they say local effects on diseased mucosa, they  
23 are talking about parts in the GI tract that have issues, that  
24 have some sort of malformation or something else, right?

25 A. The chances of dabigatran causing -- you're talking about

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1 a couple, a few cells, I mean, compared to billions of cells  
2 in the AVM. So the chances of that pill hitting that AVM and  
3 causing the bleed is close to zero.

4 Q. Zero --

5 A. It's -- just think of the surface area of the GI tract.  
6 It doesn't make sense.

7 Q. All I am asking you, ma'am, is if you can help me explain  
8 this to the jury.

9 A. Yeah.

10 Q. And what they're saying is the local effect of that  
11 Pradaxa that is going through the GI tract that didn't make it  
12 into the bloodstream may be affecting places in the GI tract.  
13 That's what they're saying.

14 I'm not saying you have to agree with it --

15 A. Right.

16 Q. -- but that's what they are saying, correct?

17 A. Well, they're not saying this. They're saying it's  
18 possible. Again, what we do in discussions is we guesstimate.

19 So I just want the jury to know that, they're just  
20 pontificating --

21 Q. I think --

22 A. -- kind of thinking it through.

23 Q. I think you've made that clear, and I don't disagree with  
24 you at all.

25 This is a hypothesis, right?

1 A. Correct.

2 Q. Based on the data that they collected in the RE-LY trial,  
3 right?

4 A. Correct.

5 Q. Okay. And this article was published in 2011, right?

6 A. Yes.

7 Q. Okay. That hypothesis came about at least as early as  
8 2011, right?

9 A. Okay.

10 Q. It's a yes or no, ma'am.

11 A. Yes.

12 Q. Okay. That's seven years ago, correct?

13 A. That is seven years ago.

14 Q. In that seven-year time period, has BI asked you or your  
15 colleagues to study this issue to try to find out if this  
16 hypothesis is correct?

17 A. Not me personally, no.

18 Q. How about anybody that you know? Have they hired anyone  
19 you know that's a GI specialist to study this issue and find  
20 out were we right about this hypothesis that we published in  
21 2011?

22 A. I don't ask my colleagues if BI has asked them that  
23 question.

24 Q. Okay. Well, we know they didn't ask you, right?

25 A. That is correct.

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1 Q. But they did hire you to testify in this case where a  
2 patient had a GI bleed in the lower gastrointestinal tract  
3 while they were on Pradaxa, right?

4 A. That is correct. But that precludes me from asking  
5 colleagues about BI.

6 Q. I'm asking about you, ma'am.

7 They didn't hire you to study this, but they did hire you  
8 to testify in this case, right?

9 A. Absolutely.

10 Q. Okay. I think you testified earlier that it would not be  
11 possible to say that Betty Knight's treatment or outcome would  
12 have been different if she had been on warfarin rather than  
13 Pradaxa when she had her bleed, right?

14 A. I agree.

15 Q. If she had been on warfarin, you agree with me that she  
16 could have been treated with either vitamin K or fresh frozen  
17 plasma to reverse the anticoagulant effect of warfarin, right?

18 A. Yes, because the half-life is so long.

19 Q. And you have found yourself fresh frozen plasma to be  
20 effective in the majority of patients you give it to who are  
21 on warfarin, right?

22 A. I give it to the minority of people that come in with GI  
23 bleeds on warfarin, but it is very effective when I do give  
24 it.

25 Q. And when you treat a life-threatening bleed, that is

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1 standard procedure for you to give either vitamin K, fresh  
2 frozen plasma or both, right?

3 A. Yes, with a qualification if I may.

4 Q. It's a yes or no.

5 When you treat a patient --

6 A. Yes.

7 Q. -- on warfarin who is having a life-threatening bleed,  
8 your standard procedure is you give them vitamin K, you give  
9 them fresh frozen plasma or you give them both, right?

10 A. If I'm concerned about them, and they're clinically  
11 unstable, the answer is yes.

12 Q. When I say life-threatening bleed, does that not mean to  
13 you that it's serious and --

14 A. We have different definitions of life-threatening bleed,  
15 so that's why I'm taking a step back.

16 Q. Okay. Your definition of life-threatening bleed, that is  
17 standard procedure for you, right?

18 A. That is correct.

19 Q. Okay. You ever given a patient platelets to treat -- to  
20 help treat a GI bleed?

21 A. I have.

22 Q. And that is if you think that they're having a problem  
23 with their platelets, right?

24 A. Yes.

25 Q. And platelets are what is affected by Plavix and aspirin,

1 right?

2 A. Correct.

3 Q. Betty Knight was not given platelets when she had her May  
4 2013 GI bleed, was she?

5 A. She didn't need to be, no.

6 Q. But she didn't get them, right?

7 A. Correct.

8 Q. Okay. And she didn't need them, right?

9 A. Correct.

10 Q. All right. I'm going to move on to No. 3.

11 I think the third question that Mr. Lewis asked you to  
12 talk about was, was Betty over-anticoagulated on Pradaxa.

13 Did I get that one right?

14 A. Correct.

15 Q. Okay. You agree with me the risk of bleed is related to  
16 the Pradaxa level in a patient's blood, right?

17 A. It can be.

18 Q. It is, right? Isn't that what the studies say?

19 A. It can be. Ah, demographic factors are really the most  
20 important thing for clinical outcome and adverse events.

21 So --

22 Q. Do you recall I asked you that same question at your  
23 deposition last year?

24 A. I do.

25 Q. Okay. And do you recall that the answer you gave me then



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1 was different than what you just told me now?

2 A. I think your -- yeah, I don't think that they're  
3 different.

4 Q. Okay. Turn to page 156 of your deposition, please,  
5 starting at line 7.

6 A. I'm sorry. Which page?

7 Q. 156.

8 A. I see it.

9 Q. At line 7, do you see I asked you: Do you agree that  
10 Pradaxa plasma concentration correlates somewhat linearly with  
11 the risk of having a bleed in a particular patient?

12 You see that?

13 A. Yes.

14 Q. And your answer was: I don't know if it's linear, but it  
15 does correlate. Right?

16 A. Correct.

17 Q. Then I asked you: And you read the Dr. Reilly article  
18 that was published in 2014, right? I think you cited it.

19 And you responded: Yes.

20 Right? Right?

21 A. Yes.

22 Q. And then my question was: He said that in his article,  
23 correct?

24 And you answered: Yes.

25 Right?

1 A. He did. Uh-huh.

2 Q. And then my last question was: And you don't disagree  
3 with that, right?

4 And your answer was: I have no reason to disagree.

5 Correct?

6 A. Correct.

7 Q. And that's the same as today. You agree that the risk of  
8 bleed correlates with the Pradaxa blood level, right?

9 A. Correct. And then I go on to say I'm not sure if you can  
10 correlate a plasma concentration with clinical outcome. So I  
11 said exactly what I just said before.

12 Q. Ma'am, did I ask you about clinical outcome?

13 A. No.

14 Q. Okay. I'm asking about bleed risk. Okay?

15 A. Okay.

16 Q. So we're going to try to stay on the same page.

17 Bleed risk correlates with Pradaxa blood level, right?

18 A. Yes.

19 Q. Okay. And you agree with me that if a patient is  
20 over-anticoagulated on Pradaxa, they have a higher risk of  
21 bleed than a patient who is not over-anticoagulated on  
22 Pradaxa?

23 A. I'm not sure what you mean by over-anticoagulated on  
24 Pradaxa. I'm not quite sure I understand that word.

25 Q. Okay. Let's look at your deposition again.

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1 A. Uh-huh.

2 Q. Page 157, line 14.

3 A. I see it.

4 Q. Do you see I asked you: Do you agree that if a patient is  
5 over-anticoagulated on Pradaxa, they have a higher risk of  
6 bleeding than a patient who is not over-anticoagulated on  
7 Pradaxa?

8 And your answer was: I'm sure it's true.  
9 Right?

10 A. Yes.

11 Q. Okay. You didn't say I don't know what  
12 over-anticoagulated on Pradaxa means, did you?

13 A. It's not a term we use routinely.

14 Q. At that time, you told me that was a true statement,  
15 right?

16 A. Yeah. But it's still not a term I would have used at that  
17 time.

18 Q. I understand that.

19 But when I asked you that question at your deposition, you  
20 agreed with me that that was a true statement, the same thing  
21 I just asked you here in court, correct?

22 A. Correct.

23 Q. Okay. You agree with me that Betty Knight was expected to  
24 have a higher Pradaxa blood level because of her age, her  
25 kidney impairment, and the fact that she was taking a drug

1 called Coreg, right?

2 A. Yes.

3 Q. Even though we expect that she would have a higher level,  
4 it's your opinion that Betty's elevated aPTT test results  
5 while she was on Pradaxa don't show that she was  
6 over-anticoagulated, right?

7 A. aPTT tests are qualitative tests. They tell you whether  
8 the patient has taken the Pradaxa. It's not going to give you  
9 exact blood levels of Pradaxa.

10 Q. I understand.

11 My question was simply, even though you expect she's going  
12 to have a high level, you don't think any of the aPTT test  
13 results that she had were evidence that she had too much  
14 Pradaxa in her blood, right?

15 A. That is correct.

16 Q. In fact, you don't think there is any level of aPTT that  
17 would tell you a patient has too much Pradaxa in their blood,  
18 right?

19 A. I mean, I'm not an aPTT -- you know, I haven't looked at  
20 people with aPTT tests that are sky high on NOACs and their  
21 incidence of bleeding. But, no, there is again no therapeutic  
22 range that has been defined.

23 Q. My question, ma'am, was you don't know what level, you  
24 don't believe there is any level of aPTT that would tell you  
25 this patient has too much Pradaxa in their blood, right?

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1 A. I can tell you an instance where that would be the case.

2 Q. Can you tell me whether or not you think there is a  
3 particular level of aPTT that tells you this patient has too  
4 much Pradaxa in their blood?

5 A. Not necessarily, no.

6 Q. You can't even tell us there's an aPTT level that says the  
7 patient's at the right level of Pradaxa in their blood, right?

8 A. Correct.

9 Q. Okay. Despite that, you agree with me that if you were  
10 able to know a level like that that would tell you aPTT-wise  
11 that a patient is at an increased risk of bleed, that is  
12 something that could be helpful to you as a  
13 gastroenterologist, right?

14 A. It could be, yes.

15 Q. Okay. And you also agree that that kind of information  
16 would be potentially useful for a physician who is prescribing  
17 Pradaxa, right?

18 A. It could be.

19 (Counsel conferring.)

20 MR. CHILDERS: May I approach, Your Honor?

21 THE COURT: You may.

22 THE WITNESS: Thank you.

23 BY MR. CHILDERS:

24 Q. You see this is a document called Summary of Product  
25 Characteristics?

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1 A. I see that.

2 Q. And it relates to Pradaxa, correct?

3 A. Yes.

4 Q. Would you turn to page 6 with me?

5 MR. CHILDERS: This is Exhibit 80. I'm sorry.

6 This is already admitted, Your Honor.

7 Would you turn to page 6, please? Blow up the middle.

8 Q. Have you ever seen this document before?

9 A. It looks familiar.

10 Q. This is the Pradaxa label that Boehringer Ingelheim gives  
11 to doctors in other countries, right?

12 A. The European.

13 Q. And if we look at the first paragraph, we see they tell  
14 doctors: The presence of lesions, conditions, procedures  
15 and/or pharmacological treatment such as NSAIDs,  
16 antiplatelets, SSRIs and SNRIs, see Section 4.5, which  
17 significantly increase the risk of major bleeding requires  
18 careful benefit-risk assessment.

19 Do you see that?

20 A. That is correct.

21 Q. And then it says: Pradaxa should only be given if the  
22 benefit outweighs the bleeding risk, correct?

23 A. Correct.

24 Q. That statement doesn't appear in the label that Boehringer  
25 Ingelheim gives to doctors here in the United States, right?

1 A. Right. The FDA has not required that statement being  
2 there.

3 Q. And from what you reviewed, Boehringer has never proposed  
4 that that statement be included in the label, correct?

5 A. I don't know if they proposed or not.

6 Q. They haven't shown you anything that showed that they  
7 proposed it to the FDA, have they?

8 A. That is correct.

9 Q. Okay. And then the next paragraph, it says: Pradaxa does  
10 not in general require routine anticoagulant monitoring.

11 Do you see that?

12 A. I do.

13 Q. That does -- that information is included in the U.S.  
14 Pradaxa label, isn't it?

15 A. It is.

16 Q. And the next sentence, though, says: However, the  
17 measurement of dabigatran-related anticoagulation may be  
18 helpful to avoid excessive high exposure to dabigatran in the  
19 presence of additional risk factors.

20 Do you see that?

21 A. I do. I see the word may.

22 Q. Were you aware that Boehringer Ingelheim believes that the  
23 measurement of dabigatran-related anticoagulation may be  
24 helpful to avoid excessive high exposure to dabigatran in the  
25 presence of additional risk factors?

1 A. Can you rephrase the beginning of the question? I'm  
2 sorry. I missed that.

3 Q. Were you aware that Boehringer Ingelheim believes that the  
4 measurement of dabigatran-related anticoagulation may be  
5 helpful to avoid excessive high exposure to dabigatran in the  
6 presence of additional risk factors?

7 A. I mean, I've read it here. And I'm sure BI is aware, but  
8 I cannot tell you why the FDA doesn't require it in the label  
9 here in the United States.

10 Q. To your knowledge, Boehringer Ingelheim has never asked  
11 that that language be included in the label in the United  
12 States, right?

13 A. Again, I don't know all the discussions that BI has had.

14 Q. I'm asking about your knowledge.

15 You don't have any knowledge, you've never seen anything  
16 to suggest to you this language has been requested by  
17 Boehringer Ingelheim to be included in the U.S. Pradaxa label,  
18 correct?

19 A. That is correct.

20 Q. Okay. And then if we look underneath, there's a Table 2.  
21 Do you see that?

22 A. I see that.

23 Q. And it says: Table 2 shows coagulation test thresholds at  
24 trough -- we've got something strange going on here.

25 Table 2 shows coagulation test thresholds at trough that



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1 may be associated with an increased risk of bleeding.

2 Do you see that?

3 A. I do.

4 Q. And then it has four different tests listed, right?

5 A. Yes.

6 Q. And one of them is the aPTT, right?

7 A. Yes.

8 Q. And in particular, what this tells a doctor -- and this,  
9 by the way, is for the 75-milligram dose -- it tells a doctor  
10 that if the aPTT test is 1.3 times the upper limit of normal,  
11 then that patient may be at an increased risk of bleed, right?

12 A. That's what this says.

13 Q. Okay. And when we say the upper limit of normal, we are  
14 talking about when you have a lab test, there is usually a  
15 range where the result falls. And if it's in that range,  
16 that's good. If it's outside that range, it's beyond the  
17 upper limit of normal. Right?

18 A. That is correct.

19 Q. Okay. Did you know this information before today?

20 A. I've read the -- I've seen the European label before.

21 Q. Okay. And in this label, the company is telling  
22 physicians not only that excessive dabigatran levels may put  
23 your patient at increased risk of bleed, but also telling them  
24 here's what you need to look for to figure out if your patient  
25 falls into that excessive dabigatran concentration, right?

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1 A. In this label. But, again, in the United States,  
2 obviously the FDA hasn't felt that that needed to be in there.

3 Q. Ma'am, have you seen any document -- has any document been  
4 provided to you to show that Boehringer Ingelheim has asked --  
5 requested that the FDA include in the label aPTT of 1.3 times  
6 upper limit of normal may indicate that patient is at an  
7 increased risk of bleed?

8 A. I'm not aware personally.

9 Q. Okay. You've not seen that document at all, right?

10 A. Not to my knowledge.

11 Q. All right. I want to talk to you, if we could, in  
12 particular about Betty Knight's aPTT levels. Okay?

13 A. Okay.

14 Q. She had some aPTT testing done before she even was on  
15 Pradaxa, right?

16 A. That is correct.

17 Q. And you've looked at some of those. In fact, we looked at  
18 them together, didn't we?

19 A. We did.

20 Q. Okay. I want to look at those again with you.

21 Again, I want you to keep in mind I'm asking you these  
22 questions in the context of question 3 here that you were  
23 asked by Mr. Lewis, was Betty over-anticoagulated on Pradaxa.

24 Okay?

25 A. Okay.

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1 MR. CHILDERS: May I approach, Your Honor?

2 THE COURT: Yes, you may.

3 THE WITNESS: Thank you.

4 MR. CHILDERS: You're welcome.

5 And this is from the medical records exhibit that has  
6 already been entered into evidence. You'll see the first  
7 page, which is 2000-2934.

8 The date is August -- sorry -- August 20th, 2011, if  
9 you look right -- I'm sorry, Gina. Can you go up a little  
10 bit.

11 Q. If you look here, you see there are some tests that were  
12 done on August 20th, 2011. Do you see that?

13 A. I do.

14 Q. Okay.

15 MR. CHILDERS: And then, Gina, if we could go down to  
16 the bottom section called Coagulation.

17 Q. And you see on that particular day, Betty Knight had an  
18 aPTT of 47?

19 Sorry. You see that?

20 A. I do.

21 Q. And that same day, she's on warfarin then, right?

22 A. Correct, but warfarin won't affect that aPTT.

23 Q. You're not familiar with the fact that warfarin can affect  
24 the aPTT?

25 A. It's extraordinarily rare.

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1 Q. The PT INR is the test you're looking at to determine if  
2 warfarin is in the right range, correct?

3 A. That is correct.

4 Q. And her PTT -- excuse me.

5 Her PT INR was 3.7, right?

6 A. That is correct.

7 Q. You agree with me Betty Knight was over-anticoagulated  
8 that day, right?

9 A. She was supratherapeutic that day.

10 Q. All right. So if I'm correct, then, you don't use the  
11 term over-anticoagulated even with warfarin patients?

12 A. Correct.

13 Q. Okay. So let me see if I can ask it in a different way.

14 Do you agree with me that Betty Knight had too much  
15 warfarin in her system that day?

16 A. Yes.

17 Q. Okay. And because of that, you say she was  
18 supratherapeutic, right?

19 A. Correct.

20 Q. If I say over-anticoagulated, you know what I mean, right?

21 A. I do.

22 Q. Okay. And that is -- what I'm saying is the same as  
23 supratherapeutic, right?

24 A. Okay.

25 Q. In your deposition, we talked about over-anticoagulated

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1 the whole time. Do you remember that?

2 A. I do. You insist on using it.

3 Q. And you didn't seem to have a problem with it then,  
4 correct?

5 A. That -- I -- that is not true, but --

6 Q. You just didn't tell me you had a problem with it.

7 A. I guess.

8 Q. Okay. Fair enough.

9 Okay. So we know this day she was over-anticoagulated.  
10 Her aPTT happened to be 47, correct?

11 A. She was supratherapeutic on coumadin, which should not  
12 affect that PTT level.

13 Q. Her PTT was high, right?

14 A. The PTT was high for I don't know what reason.

15 Q. Okay.

16 A. But it didn't have to do with the coumadin. I want to  
17 make that very clear to the jury.

18 Q. And it's your testimony that coumadin will not affect the  
19 aPTT; is that right?

20 A. It is very rare. I see people on coumadin a lot, and it's  
21 not the aPTT test that we follow with coumadin. It's the PT  
22 INR.

23 Q. I understand that.

24 My question to you is, is it your testimony that coumadin  
25 will not affect the aPTT?

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1 A. It -- it can rarely.

2 Q. Okay.

3 A. I see lots of patients on coumadin who have normal PTTs.  
4 So to assume that this PTT was elevated because she was on  
5 warfarin I think is incorrect.

6 Q. That wasn't my question.

7 My question is simply this. You agree with me she was  
8 over-anticoagulated that day, right?

9 A. She was supratherapeutic on her coumadin is what I'll  
10 agree with, correct.

11 Q. Okay. And by that she had too much coumadin in her  
12 system?

13 A. Correct.

14 Q. She was outside the therapeutic range?

15 A. Correct.

16 Q. That same day, her aPTT was 47, correct?

17 A. Correct.

18 Q. Okay. And then if we could turn to the next page.

19 Do you -- I'm sorry. Two pages over.

20 A. Sure.

21 MR. CHILDERS: Yes. I'm sorry. To 4002.

22 Q. Okay. Do you see this is, again, a lab test result  
23 document for Betty Knight?

24 A. Yeah, I do.

25 Q. And this one in particular is in May of 2013, correct?

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1 A. I see it.

2 MR. CHILDERS: Okay. And if we look under this one,  
3 Gina, for May 21st, 2013.

4 Q. Do you see that she had her coagulation panel run again?

5 A. I do.

6 Q. And on that day, although it's a little hard to read, do  
7 you see her aPTT was 47?

8 A. I do.

9 Q. And that was shown to be high, correct?

10 A. It's above normal for their range, correct.

11 Q. That's exactly the same number as it was when we looked,  
12 and you agreed with me, that she was supratherapeutic on  
13 warfarin back in 2011, right?

14 A. That is correct. But that doesn't have anything to do  
15 with the PTT.

16 Q. Okay. Let's go then to --

17 MR. CHILDERS: May I approach, Your Honor?

18 THE COURT: You may.

19 MR. CHILDERS: I'm going to hand you another --

20 THE WITNESS: Thank you. Appreciate it.

21 MR. CHILDERS: -- set of records. Again, these are  
22 from the medical exhibit that has already been admitted. We  
23 start with page 2641.

24 Q. You see that?

25 A. I see this.

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1 Q. And this is dated April 9th, 2009, right?

2 A. I see that.

3 Q. Ms. Knight was on warfarin at that point, right?

4 A. Correct.

5 Q. Okay.

6 MR. CHILDERS: If we could go down, Gina.

7 Q. They checked her aPTT as well as her PT INR, right?

8 A. Yes.

9 Q. Okay. And her aPTT that day was 62, correct?

10 A. Correct.

11 Q. And it was found to be high, right?

12 A. High for their reference range, yes.

13 Q. And then if we look at her PT INR, it was 4.3, correct?

14 A. That is correct.

15 Q. That's supratherapeutic on warfarin, correct?

16 A. The INR indicates that, yes, she is supratherapeutic on  
17 warfarin.

18 Q. So she has too much anticoagulant in her blood, right?

19 A. Based on the INR alone, yes.

20 Q. Okay. And then if we could -- if you could turn the page  
21 in your chart.

22 MR. CHILDERS: And, Gina, I'm going to ask you to put  
23 up page 2 -- I'm sorry -- 3759.

24 Q. Do you see this is a clinical report from August 22nd,  
25 2013?



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1 A. I see it.

2 Q. That's a little over a week before Betty passed away,  
3 right?

4 A. Yes.

5 Q. Okay. And Betty was on Pradaxa at that point?

6 A. Correct.

7 Q. Okay. If we could turn to the third page.

8 Do you see that her aPTT was checked that day?

9 A. I do.

10 Q. And it was 62, right?

11 A. Correct.

12 Q. That's the exact same level it was when she had too much  
13 anticoagulant in her system back in April of 2009, right?

14 A. Too much warfarin.

15 Q. Which is an anticoagulant, correct?

16 A. That is correct.

17 Q. Okay. I think you testified earlier that when you looked  
18 at the records, you didn't see any sign of Mrs. Knight having  
19 a bleed after May of 2013; is that right?

20 A. That is correct.

21 Q. Okay. Well, about a week after this is the August 22nd,  
22 2013 record.

23 You agree with me that Betty had blood in her urine,  
24 right?

25 A. She had -- they noted red blood.

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1 Q. Okay. That was the day before she went to the hospital on  
2 September 1st, right?

3 A. Right. But her urinalysis was negative.

4 Q. There was blood found in her urine on the urinalysis.

5 A. Barely.

6 Q. Was there blood in the urine?

7 A. Very little. It's microscopic. They needed a microscope  
8 to see the blood cells.

9 Q. They didn't need a microscope for her to see the blood  
10 cells before she got to the hospital, right? She saw it in  
11 her urine; isn't that right?

12 A. She saw some blood in her urine, correct.

13 Q. Okay. And then when she got to the hospital, they did a  
14 urinalysis and said, yep, there's blood in the urine, correct?

15 A. Yes. And there was also bacteria, which is very  
16 suggestive of a urinary tract infection, which she's had in  
17 the past.

18 Q. Okay. My question was only was there blood in her urine,  
19 ma'am.

20 A. Sorry.

21 Q. Was there blood in her urine?

22 A. Yes.

23 Q. That was the day before she passed, right?

24 A. It was unfortunately, yes.

25 Q. And she was still on Pradaxa at that time?

1 A. She was.

2 Q. Okay. I think the next question you were asked was, did  
3 Betty's May 2013 GI bleed contribute to her death.

4 Do you recall being asked that?

5 A. I do.

6 Q. Okay. And I think you said unequivocally, no, you don't  
7 believe it did, right?

8 A. I don't believe it did, correct.

9 Q. In fact, I think you told us that you don't even think  
10 Betty had what is considered a severe bleed in May of 2013,  
11 right?

12 A. What I said it wasn't hemodynamically unstable.

13 I wouldn't characterize it -- for all the GI bleeds that I  
14 see, it's not severe in that she wasn't clinically unstable,  
15 and she did not need the intensive care unit.

16 Q. You don't think she had a severe bleed in May of 2013?

17 A. That is correct.

18 Q. You reviewed Dr. Abdelgaber's deposition testimony in this  
19 case, didn't you?

20 A. I can't recall offhand but, yeah, I'm sure at some point.

21 Q. Do you know who Dr. Abdelgaber is?

22 A. It's her primary care physician.

23 Q. He is the one who admitted her to the hospital for the  
24 bleed, right?

25 A. Yes.

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1 Q. You listed his deposition as something you relied on for  
2 your opinions in this case, right?

3 A. Correct.

4 Q. Okay. But you can't remember -- see if I can refresh your  
5 recollection.

6 Is this --

7 MR. LEWIS: Your Honor, I'm going to object to this,  
8 playing somebody else's deposition -- showing somebody else's  
9 deposition.

10 THE COURT: Well, whose deposition is this?

11 MR. CHILDERS: This is Dr. Abdelgaber.

12 THE COURT: Well, you can ask her --

13 MR. CHILDERS: Okay.

14 THE COURT: -- a question to see if it refreshes her  
15 recollection about what he said.

16 MR. CHILDERS: Fair enough. Let me just do this if I  
17 could, Your Honor.

18 May I approach?

19 THE COURT: Yes.

20 MR. CHILDERS: I'm just going to hand you this one  
21 page of testimony --

22 THE WITNESS: I'm sorry. What are you handing me?  
23 What is it?

24 MR. CHILDERS: This is a page from Dr. Abdelgaber's  
25 testimony.

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1 Q. You relied on this for your opinions in this case, right?

2 A. I see it.

3 Q. Do you see line 14, where he was asked: Did you feel at  
4 any time during her admission her life was in danger from the  
5 GI bleed?

6 And then he said: I -- that's why I admitted her to the  
7 hospital?

8 A. Yes.

9 Q. So does that refresh your recollection about Dr.  
10 Abdelgaber's testimony in that regard?

11 A. Yeah. It's --

12 Q. Okay.

13 A. -- no different than what I said.

14 Q. And you don't disagree with Dr. Abdelgaber, correct?

15 A. No. I would have admitted her to the hospital as well.

16 Q. Okay. And you looked at the discharge summary from when  
17 Betty got out of the hospital, right?

18 A. I did.

19 Q. And you relied on that for your opinions in this case?

20 A. I did.

21 Q. And you looked at --

22 MR. CHILDERS: May I approach, Your Honor?

23 THE COURT: You may.

24 MR. CHILDERS: I'm going to hand you the --

25 THE WITNESS: Thank you.

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- 1 MR. CHILDERS: -- front page of the discharge summary.
- 2 Q. You see what I've handed you is the page with the
- 3 discharge diagnoses from the discharge summary?
- 4 A. I see it.
- 5 Q. And you reviewed this as you formulated your opinions in
- 6 this case?
- 7 A. I did.
- 8 Q. And you see the first one under Discharge Diagnoses is:
- 9 Severe gastrointestinal blood loss, anemia with symptomatic
- 10 initially, correct?
- 11 A. That is correct.
- 12 Q. And then if we turn in your exhibit one page -- this is
- 13 going to be page No. 3959, Gina -- this is the discharge
- 14 summary from when Betty got out of skilled nursing after being
- 15 in the hospital, right?
- 16 A. Yes.
- 17 Q. Okay. And if we look under Discharge Diagnoses, No. 1
- 18 says: General debility stemming from various medical problems
- 19 including chronic anemia stemming from severe gastrointestinal
- 20 bleed loss due to AV malformation, correct?
- 21 A. Yes.
- 22 Q. I take it you disagree with Betty's doctors who wrote down
- 23 that she had severe gastrointestinal blood loss?
- 24 A. As a gastroenterologist, I do disagree.
- 25 Q. Okay. So you don't agree with the diagnosis on either of

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1 these documents that we just looked at?

2 A. We agree that she's had a GI bleed. It's just the  
3 severity of the bleed I disagree with.

4 Q. Okay.

5 A. Yes.

6 MR. CHILDERS: Let me show you Exhibit --

7 (Counsel conferring.)

8 MR. CHILDERS: May I approach, Your Honor?

9 THE COURT: Yes.

10 THE WITNESS: Thank you.

11 MR. CHILDERS: I'm handing you the Pradaxa label,  
12 physician label for when it was first put on the market.

13 Q. You see that?

14 A. I do.

15 Q. And if you could turn with me to page 3, there's a Section  
16 6.1.

17 A. I see that.

18 Q. Okay. And if you look a little farther down on 6.1, about  
19 halfway down the page, there's a section called Bleeding.

20 A. Yes.

21 Q. Okay.

22 MR. CHILDERS: I understand from defendants this is  
23 already admitted. I didn't think it was, but --

24 THE COURT: All right. You want to state the number?

25 MR. CHILDERS: It's Exhibit 86.

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1 MS. JONES: If it's not admitted, there's no objection  
2 to the admission of this.

3 THE COURT: All right. You may publish it.

4 MR. CHILDERS: And then if we could --

5 Q. This is talking about the RE-LY study, right?

6 A. It is.

7 Q. And you talked with Mr. Lewis a little bit about how that  
8 RE-LY study was set up, and how they categorized bleeding  
9 events, right?

10 A. Correct.

11 Q. Okay. And what they said -- if you go to right here,  
12 Gina -- is: A life-threatening bleed met one or more of the  
13 following criteria.

14 The first one is fatal. The second is symptomatic  
15 intracranial bleed. Then reduction in hemoglobin of at least  
16 5 grams per deciliter. And then transfusion of at least four  
17 units of blood. Then associated with hypotension requiring  
18 the use of intravenous inotropic agents. And then finally  
19 necessitating surgical intervention.

20 Correct?

21 A. I see that.

22 Q. In this particular case, in Ms. Knight's case, she had a  
23 reduction in her hemoglobin of at least 5 grams per deciliter,  
24 correct?

25 A. Incorrect.



1 Q. How much was her --

2 A. Her baseline is 5 -- or a 10. She went to 6.4.

3 Q. Okay. She had a transfusion of at least four units of  
4 blood. We can agree on that?

5 A. She did have four units of blood.

6 Q. Okay. So she meets the criteria or met the criteria from  
7 the RE-LY trial for being categorized as a life-threatening  
8 bleed, right?

9 A. Correct.

10 Q. Okay.

11 MR. CHILDERS: You can take that down, Gina.

12 Q. If I understood your testimony correctly, you don't  
13 disagree with the RE-LY criteria, you just don't use it; is  
14 that right?

15 A. Correct. It's very different. You have to have objective  
16 criteria when you are doing a study, but that is not how we  
17 practice medicine as physicians.

18 And as gastroenterologists, you know, we have different  
19 ways of assessing how severe bleeding is. And I think I've  
20 explained to the jury and you that we use clinical signs  
21 and --

22 Q. Understood.

23 And when you say doctors do it -- I guess treating doctors  
24 do it differently, you're not including Ms. Knight's doctors  
25 who said she had a severe bleed when they wrote the discharge

1 diagnoses, correct?

2 A. Again, I'm not disagreeing with the word bleed. I think  
3 the severity of it is debatable.

4 Q. Right.

5 And so you disagree with what her doctors wrote in the  
6 discharge diagnoses?

7 A. Yes, I do.

8 Q. Okay. Let's talk about how significant the bleed was to  
9 Betty's health. Okay?

10 A. Okay.

11 Q. I understand that it's very unusual for you to have to  
12 send a GI bleed patient to skilled nursing after you've  
13 treated them; is that right?

14 A. That is correct.

15 Q. And I think you testified earlier today that AVM bleeds,  
16 which is what Betty had, should only require hospitalization  
17 of a couple of days.

18 Is that what you told us?

19 A. Yeah, a few days. That's correct.

20 Q. Okay. Betty was in the hospital for five days, right?

21 A. I believe she was in the hospital for three.

22 Q. Okay. Well, if we look at the --

23 A. But it may --

24 Q. We can look again if we need to at Dr. Abdelgaber's  
25 deposition --

1 A. Yeah.

2 Q. -- but, either way, she never left the hospital between  
3 May 20th and June 8th, right?

4 A. That's incorrect.

5 Q. She never left the hospital facility that included the  
6 skilled nursing between May 20th and June 8th, correct?

7 A. Right. The only reason why is because the skilled nursing  
8 was in the physical hospital. You can't assume that that's  
9 the entire hospitalization.

10 She was in the hospital for three days or five -- I think  
11 it was three -- and then she was discharged. If the facility  
12 was in a different building --

13 Q. Did you read -- you read Dr. Abdelgaber's deposition?

14 A. I did.

15 Q. You saw where he said the skilled nursing is part of the  
16 hospital, it's just in a different section.

17 Do you recall that?

18 A. Right. Physically it is part -- in the same --

19 Q. Okay.

20 A. But what I'm saying is in many institutions, that's not  
21 the case, and you can't consider that the entire  
22 hospitalization.

23 The acuity of the GI bleed was the first few days. She  
24 was discharged, there was a discharge summary, and  
25 subsequently she was in rehab.

1 Q. And that's what we're talking about --

2 A. Correct.

3 Q. -- right?

4 When she got finished with her inpatient hospital  
5 treatment, they didn't send her home, right?

6 A. That is correct.

7 Q. She went to skilled nursing, right?

8 A. That is correct.

9 Q. For 15 days.

10 A. That is correct.

11 Q. Your personal practice is you hardly ever send a patient  
12 to skilled nursing after a GI bleed, right?

13 A. That is correct. But Ms. Knight's been to that same  
14 nursing facility multiple times in the past.

15 Q. The last time she was there was 2008, right?

16 A. I believe she had been there before, but I can't tell you  
17 every single time she's been there.

18 Q. You guys made a good chart that we can look at where you  
19 actually put that information, right?

20 Remember this chart?

21 A. I do remember that chart.

22 Q. The only time on here that you noted that she went to  
23 skilled nursing was in 2008, right?

24 A. That is correct.

25 Q. Okay. And by the way, I noticed here on this entry for

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1 November 13th to 19th, that's when you said she had a GI  
2 bleed, right?

3 A. Correct.

4 Q. It doesn't say anything about a GI bleed on your chart,  
5 does it?

6 A. No. I think he's putting exactly what was in the record.

7 Q. And the record didn't say GI bleed, did it?

8 A. Not -- not the chief complaint, that is correct.

9 Q. Okay. If we could go back to the discharge summary from  
10 the skilled nursing facility being 3959, there's a section  
11 here called Hospital Course.

12 Do you see that down at the bottom?

13 A. Is this in the same packet you gave me?

14 Q. I'm sorry.

15 A. I'm sorry.

16 Q. It was the one we were just looking at prior to the bleed.

17 A. Okay.

18 Q. The second page.

19 Do you see it says Hospital Course?

20 A. I'm not trying to be difficult. I don't.

21 Q. If you look on the screen --

22 THE COURT: Look at the monitor and see if you can  
23 find it.

24 MR. CHILDERS: -- that should help.

25 THE WITNESS: Sorry.

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1 MR. CHILDERS: That's okay.

2 Q. Do you see that it says: Patient was admitted to our  
3 skilled nursing unit due to general debility stemming from  
4 anemia secondary to chronic blood loss.

5 Do you see that?

6 A. That is correct.

7 Q. And in fact, that's not correct.

8 You remember from Dr. Abdelgaber's deposition he said the  
9 word chronic should have said acute, that that was a mistake  
10 in this record, right?

11 A. I saw that he changed it during the deposition, yes.

12 Q. And you agree with him changing it to acute, correct?

13 A. I mean, she's also had chronic blood loss, so I think  
14 they're both correct.

15 Q. Well, according to the doctor who treated her in the  
16 hospital, it should have said acute blood loss, correct?

17 A. I'm not arguing with that.

18 Q. And acute blood loss means the blood loss that she was  
19 experiencing when she had to have the colonoscopy and the  
20 clipping, right?

21 A. That is correct.

22 Q. Okay. Now we talked about some other hospitalizations or  
23 you talked about some other hospitalizations that Betty had,  
24 including one in April 2013 to have stents placed?

25 A. Correct.

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1 Q. Betty did not have to go to skilled nursing after having  
2 the stents placed, right?

3 A. That is correct.

4 Q. She went home, right?

5 A. She had home health.

6 Q. Home health didn't live in her house, right? They came  
7 occasionally during the week to help her, right?

8 A. We don't know how often they came but, yes, they came.

9 Q. I thought you looked at all the home health records.

10 A. I did look at the home health records.

11 Q. So you know exactly how many times they came?

12 A. Yeah, but I can't tell you after that hospitalization  
13 every single time that they came in.

14 Q. Well, you agree with me they weren't there every day,  
15 right?

16 A. Yes.

17 Q. And she was able to go home even though they weren't there  
18 every day and live there by herself, right?

19 A. Ah, she had full family support.

20 Q. Did her family live at her house with her?

21 A. No, I don't think so.

22 Q. Okay. You read in Dr. Abdelgaber's deposition that he  
23 testified that Betty did not seem to ever get better or bounce  
24 back from the May 2013 GI bleed, didn't you?

25 A. I saw that.

1 Q. That's what he said, right?

2 A. That is correct.

3 Q. And you don't disagree with Dr. Abdelgaber, correct?

4 A. I mean, again, Ms. Knight had multiple, you know,  
5 co-morbidities. She had multiple medical problems. She's  
6 been in and out of the hospital in 2008, 2011. So -- and time  
7 has gone by. She's now 84. She was 83 at the time of the  
8 stents. Unfortunately things happen over time.

9 Q. Doctor, you don't disagree with Dr. Abdelgaber's statement  
10 that Betty did not seem to ever get better or bounce back from  
11 the May 2013 GI bleed, correct?

12 A. I can't disagree with him, that is correct.

13 Q. And you don't disagree with him, correct?

14 A. I wasn't -- I mean --

15 Q. Right.

16 You weren't there?

17 A. No.

18 Q. He was, correct?

19 A. He was there.

20 Q. And that's what he testified to, correct?

21 A. That's what he testified, correct.

22 Q. In fact, you will defer to Dr. Abdelgaber's opinion in  
23 that, correct?

24 A. Yes.

25 Q. Okay. All right. The last thing I thought you were asked



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1 was, did the Pradaxa label --

2 THE COURT: Why don't you wait until you finish  
3 writing so you can use the microphone so we can hear you.

4 MR. CHILDERS: I'm sorry.

5 THE COURT: Is it on? There it is.

6 MR. CHILDERS: Sorry. Can you hear me now, Judge?

7 THE COURT: Yes.

8 MR. CHILDERS: Did the Pradaxa label adequately warn  
9 about Pradaxa's bleed risk.

10 Q. Is that right?

11 A. That is correct.

12 Q. Okay. You've never prescribed Pradaxa, have you?

13 A. I have not.

14 Q. You've never once used the Pradaxa label to decide if  
15 Pradaxa is the right anticoagulant medication for a patient,  
16 have you?

17 A. I've looked at the label.

18 Q. I didn't ask you that, ma'am.

19 Have you ever used the label to decide if Pradaxa is the  
20 correct anticoagulant for a particular patient?

21 A. I don't make that decision --

22 Q. You've never done that --

23 A. -- that's correct.

24 Q. -- right?

25 A. I don't make the decision as to what anticoagulant

1 somebody goes on.

2 Q. Okay. And so when you are giving your opinions about the  
3 adequacy of the Pradaxa label and the warnings, that's not  
4 something in practice that you actually do for particular  
5 patients, right?

6 A. I do it for other medications, so I feel -- I read labels  
7 all the time. So I'm very -- I'm familiar with reading  
8 labels.

9 Q. The question is, do you do it for Pradaxa?

10 A. Not specifically for -- to make a decision on whether  
11 somebody should be on Pradaxa or not. I do not write the  
12 prescription, that is correct.

13 Q. You understand that's why we're here, whether or not Betty  
14 Knight should have been on Pradaxa?

15 You understand that, right?

16 A. Yes.

17 Q. Okay. You would not second-guess a doctor -- another  
18 doctor's choice of anticoagulant for their patient, would you?

19 A. No. I agree with her physicians who put her on Pradaxa.

20 Q. I'm talking about any anticoagulant.

21 You would never step in and say, hey, Doctor X, I disagree  
22 with what you prescribed to this patient, right?

23 A. I can as a consulting gastroenterologist or somebody -- if  
24 somebody is on my inpatient service, I can say, you know what,  
25 I don't agree with the cardiologist. But that rarely occurs.

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1 Q. You've never done that, have you?

2 A. I have.

3 And if you're going to ask time frame, it was last month.

4 Q. Okay. So the only time you've ever done that was last  
5 month, right?

6 A. Yes.

7 Q. Okay. Which is after the time I took your deposition in  
8 this case, right?

9 A. Absolutely, which was nine months ago.

10 Q. How long have you -- did you tell us you've been  
11 practicing medicine?

12 A. 16 years as an attending physician.

13 Q. Okay. And so the only time you've ever done that was last  
14 month?

15 A. Yeah.

16 Q. Okay.

17 A. I can -- we as prescribing -- we can talk to cardiologists  
18 and decide, especially if somebody is having a GI bleed,  
19 whether to restart it, what to start. I mean, that's part of  
20 our daily practice.

21 Q. That wasn't my question, though.

22 My question was whether or not you would second-guess the  
23 anticoagulant choice that was made by another physician for a  
24 patient.

25 A. The word second-guess is --

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1 Q. You didn't have a problem answering when I asked you that  
2 question at your deposition; do you recall?

3 A. I do recall.

4 Q. Okay. And when I asked you, you wouldn't second-guess  
5 that decision, you said that's correct, didn't you?

6 A. Yeah. I'm not going to second-guess one of our  
7 cardiologists, but I will definitely put my input in there if  
8 I need to.

9 Q. I believe -- but you just don't actually change the  
10 medication ever, except for this one time --

11 A. I don't personally write the prescription, correct.

12 Q. All right. I believe you testified -- and I wrote this  
13 down again, so if I got it wrong, I apologize -- but the  
14 Pradaxa doctor label, which you have a copy in front of you,  
15 Exhibit 86, adequately describes the Pradaxa bleed risk,  
16 right?

17 A. Correct.

18 Q. Okay. You have the label in front of you.

19 A. I have the two thousand -- I have the old label in front  
20 of me.

21 Q. Okay. And that label was in existence when --

22 MR. CHILDERS: Which one is that?

23 (Plaintiffs' counsel conferring.)

24 MR. CHILDERS: All right. Fair enough.

25 Q. Can you tell me -- can you tell the jury where that label

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1 tells doctors how much severe kidney impairment increases a  
2 Pradaxa patient's bleed risk?

3 A. Are you talking specifically about the older label --

4 Q. You can look at --

5 A. -- from 2011?

6 Q. You're welcome to look at any Pradaxa label you want and  
7 answer that question for me.

8 Where in the label does it tell a doctor how much severe  
9 kidney impairment increases a patient's bleed risk if they're  
10 on Pradaxa?

11 A. It does not.

12 Q. Okay. Can you tell me where in any Pradaxa label you have  
13 ever reviewed that tells a doctor how much taking a P-gp  
14 inhibitor medication increases a patient's bleed risk?

15 A. It doesn't.

16 It does specify that it does increase with the P-gp  
17 inhibitors, and it does specify specifically that it does  
18 increase based on creatinine clearance, which is a function  
19 of -- of the way the kidneys work.

20 Q. It just doesn't tell the doctor how much that increase is,  
21 right?

22 A. That is correct.

23 Q. How much -- can you tell the jury where any of the Pradaxa  
24 labels, ah, tell doctors how much being over the age of 80  
25 increases a Pradaxa patient's bleed risk?

1 A. In terms of percentage?

2 Q. Yes.

3 A. No, it does not.

4 But it does -- you know, again, it does state specifically  
5 for kidney. And it states specifically for P-gp inhibitors  
6 that it does increase, potentially increase the levels.

7 Q. Without any details about how much that increase would be,  
8 right?

9 A. That is correct.

10 Q. And then could you tell the jury where any of the Pradaxa  
11 labels that you've relied on tell a doctor how much being a  
12 female increases the bleed risk for a patient on Pradaxa?

13 A. It does not.

14 Q. Can you tell the jury where any of the Pradaxa labels you  
15 rely on tell a physician how much having diabetes increases  
16 your risk of having a bleed on Pradaxa?

17 A. It doesn't tell you about percentage, that is correct.

18 Q. Does it say you have an increased risk of bleed if you  
19 have diabetes?

20 A. I don't know, sir. I'd have to look at the label for  
21 2013. Do you want to give it to me?

22 Q. Look at the one that is in front of you.

23 A. This one is old.

24 Q. Does it say it?

25 A. This is obsolete, though. This is not at the time of her

1 bleed.

2 Q. Well, it's at the time of when she was prescribed the  
3 drug.

4 A. Correct, but she's had multiple people -- I mean, she's  
5 been prescribed the drug --

6 Q. Understood.

7 Tell me where it says diabetes increases your bleed risk.

8 A. It does not.

9 Q. Okay. Can you tell the jury where that label or any label  
10 that you have seen tells a doctor how much a patient's bleed  
11 risk is increased if they have reflux or GERD?

12 A. It does not.

13 Q. Okay. Can you tell the jury how much -- excuse me.

14 Can you tell the jury where in that label it tells a  
15 doctor how much giving a patient aspirin while they're on  
16 Pradaxa increases the patient's bleed risk?

17 A. It doesn't give you a percentage, but it does tell you it  
18 increases the bleeding risk for -- for many of these things  
19 you're talking about.

20 Q. Can you tell the jury where in the label it tells doctors  
21 how much bleed risk is increased for a patient who is taking  
22 Plavix?

23 A. It doesn't have a percentage, but it does state that it  
24 can increase, your bleeding risk does increase while you're on  
25 both.

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1 Q. When Betty Knight started taking Pradaxa, do you agree  
2 with me that the doctor label did not tell doctors, nurses,  
3 whoever was reading it, not to give Pradaxa to a patient with  
4 severe renal -- severe kidney impairment who was also taking a  
5 P-gp inhibitor?

6 A. It said to tell your physicians what medications you're  
7 on, and that you're at increased risk if you have -- you're  
8 age greater than 75.

9 Q. I'm talking about the doctor label, ma'am.

10 A. The doctor or patient?

11 Q. The doctor label.

12 A. Okay.

13 Q. You agree with me when Betty Knight was started on  
14 Pradaxa --

15 A. Okay. This label, okay.

16 Q. -- it did not say do not give Pradaxa to a patient who has  
17 severe kidney impairment who is also taking a P-gp inhibitor  
18 medication?

19 A. That is correct. But it did at the time of her bleed.

20 Q. Can you tell me where in any label for Pradaxa you've ever  
21 seen it tells physicians Coreg is a P-gp inhibitor?

22 A. It doesn't say that specifically. But we, as prescribing  
23 physicians, know that.

24 Q. Can you list for me every drug that is a P-gp inhibitor?

25 A. No, I cannot. Carvedilol is a very or Coreg is a very



1 commonly used drug.

2 Q. Especially in atrial fibrillation patients, right?

3 A. Yes.

4 Q. One of those commonly used drugs you would expect the  
5 company to say don't give this drug to a severely renally  
6 impaired patient who is taking Pradaxa, right?

7 A. No. Labels do not treat patients, physicians do. I mean,  
8 you're kind of ignoring all of the benefits of the drug and  
9 just concentrating on one thing.

10 It's not obsolete. It's not a bad thing Ms. Knight was on  
11 this drug. I mean, we're preventing strokes. We're  
12 preventing emboli. It's not a label that -- we're not  
13 treating the patient based on a label.

14 Q. Well, the label didn't tell Dr. MacFarland or her nurse,  
15 Betty Knight's not a patient who this medicine should be given  
16 to. It didn't say that when they prescribed it to her, did  
17 it?

18 A. No. But, again, she was prescribed the medication over  
19 and over again. And we as physicians will re-review labels  
20 all the time, and it was on the label from 2013.

21 Q. Okay. You read Dr. MacFarland's deposition, correct?

22 A. I have.

23 Q. Okay. And in that deposition, she said she only ever got  
24 one dear doctor letter, and it related to mechanical heart  
25 valves, correct?

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1 A. That's a dear doctor -- that's different than the --

2 Q. Understood.

3 A. -- than the label.

4 Q. So when the label was changed to say a patient like Betty  
5 Knight shouldn't get Pradaxa, she didn't get a letter like  
6 that, did she?

7 A. No.

8 Q. Okay. Nobody in the whole country got a letter like that  
9 when that change was made to the label, did they?

10 A. They did not, to my knowledge.

11 Q. Do you agree with me that knowing that a patient who has  
12 severe renal impairment and is taking Coreg should not take  
13 Pradaxa is important information for a doctor to know?

14 A. It's information that is in the label.

15 Q. It wasn't at the time she got prescribed the drug by Dr.  
16 MacFarland's office, correct?

17 A. But you can't go based on a label that is two years old  
18 when everything is -- you're talking about the GI bleed in  
19 2013. It's a little bit unfair to use an obsolete label.

20 I mean, with time comes knowledge. And in 2013, when they  
21 renewed her -- you know, renewed her Pradaxa, the label is  
22 from 2013, and that's the one I think we should be reviewing.

23 Q. Ma'am, you talked about whether or not the Pradaxa label  
24 adequately warns about Pradaxa's bleed risk.

25 You weren't talking about one label, you were talking

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1 about all of them over time, weren't you?

2 A. I'm talking over time, correct.

3 Q. Okay. And you agree with me, when Betty Knight was  
4 started on Pradaxa, her doctors were not told this medication  
5 should not be given to a patient with severe kidney impairment  
6 who was taking a drug like Coreg, correct?

7 A. I think should is too absolute.

8 Q. It says should be avoided in the label, doesn't it?

9 A. Correct. But that doesn't mean it's wrong for her.

10 Q. That's information that the doctor has to know to be able  
11 to make that decision, correct?

12 A. That is correct.

13 Q. Okay. And like you said, Boehringer did add that  
14 information to the label after Betty Knight had already  
15 started it.

16 A. Correct.

17 Q. But as you agreed with me, they didn't communicate that in  
18 writing, that change, they didn't send a letter to Dr.  
19 MacFarland or any other doctor in the country saying, hey, we  
20 changed the label to have this new information, correct?

21 A. That is correct.

22 Q. Okay.

23 A. But we as physicians re-review labels intermittently, from  
24 time to time, so that's pretty standard of care.

25 Q. You agree with me the words Coreg or carvedilol have never

1 appeared in the Pradaxa label, right?

2 A. No.

3 Q. And they have never appeared in the patient Medication  
4 Guide, correct?

5 A. I would have to recheck that. I don't think so.

6 Q. Well, you went through the Guide with Mr. Lewis and said  
7 there are some medications that are listed, and some aren't,  
8 right?

9 A. Right.

10 Q. If Coreg was in there, you would have told us, right?

11 A. That is correct.

12 Q. Okay. And you didn't tell us that, did you?

13 A. No.

14 Q. The label, the doctor label -- I want to make sure we are  
15 clear on this --

16 A. Uh-huh.

17 Q. -- did not tell Dr. MacFarland and her nurse that Pradaxa  
18 had never been tested in patients who had severe kidney  
19 impairment when they started Betty Knight on Pradaxa, right?

20 A. Can you -- I'm sorry. I missed the first part.

21 Q. The doctor label --

22 A. Uh-huh.

23 Q. -- did not tell Dr. MacFarland or her nurse that Pradaxa  
24 had never been tested in patients with severe kidney  
25 impairment when they started Betty on Pradaxa in October of

1 2011?

2 A. It doesn't say that, correct.

3 Q. The label also didn't tell Dr. MacFarland or her nurse  
4 that the 75-milligram Pradaxa dose had never been tested in  
5 atrial fibrillation patients, correct?

6 A. That is correct.

7 But it was a model, it was modeled off of the RE-LY study.  
8 And the FDA actually modeled that dose, they came up with that  
9 dose, and BI independently did a study. And so that's how  
10 that dose came -- came to fruition.

11 Q. The independent study you are talking about, that's not  
12 with patients, right? That was modeling as well?

13 A. Right. It's modeling.

14 Q. Understood.

15 A. And the FDA is full of very bright people, so it's hard  
16 to, ah --

17 Q. We all understand that.

18 A. -- sway them.

19 Q. The company didn't tell the doctors that this is only  
20 based on modeling data, we didn't actually test it in  
21 patients, did it?

22 A. It doesn't say it specifically, that's correct.

23 Q. Okay. You said you also reviewed the Medication Guide  
24 portions of all of the labels that you were given, correct,  
25 the Pradaxa labels?

1 A. Yes.

2 Q. And you agree with me that none of those Medication Guides  
3 have ever included information saying that Pradaxa has not  
4 been tested in atrial fibrillation patients with severe renal  
5 impairment, right?

6 A. Yes.

7 Q. Okay. And you agree with me that the Medication Guide,  
8 patient Medication Guide has never said the 75-milligram dose  
9 of Pradaxa was never actually tested in atrial fibrillation  
10 patients, correct?

11 A. That is correct.

12 But the medication -- I mean, are we talking about the  
13 patient guide now?

14 Q. Yes.

15 A. The patient guide says discusses all of your medications  
16 with your physician. And if you want additional information,  
17 you can go and get additional information such as this guide,  
18 and they provide a phone number. So it's not like they  
19 provide absolutely no information.

20 Q. I didn't ask you if they provide no information.

21 I'm asking very specifically if certain information has  
22 ever been included in those Medication Guides. Okay?

23 A. Correct.

24 Q. The next -- and you agree with me the fact that the  
25 75-milligram dose was not tested in patients for AFib, it

1 doesn't say that in the Medication Guide --

2 A. That's correct.

3 Q. And the Medication Guide has never said patients with  
4 severe kidney impairment who are also taking a P-gp inhibitor  
5 should avoid Pradaxa, right?

6 A. In the Medication Guide?

7 Q. That's right.

8 A. No.

9 But they say -- they specifically say renal -- renal  
10 problems, discuss with their physician, that you're at  
11 increased risk of bleeding.

12 (Plaintiffs' counsel conferring.)

13 BY MR. CHILDERS:

14 Q. If we could go back to the Medication Guide, page 12.

15 A. I'm sorry. Which one?

16 Q. I'm sorry. It's in the other binder that Mr. Lewis gave  
17 you. It's Exhibit 5889.

18 A. I'll look here.

19 Q. Okay. That would be fine.

20 And this is a Medication Guide and the label that you and  
21 Mr. Lewis talked about, right?

22 A. It is.

23 Q. And if we look under the you may have a higher risk of  
24 bleeding if you take Pradaxa and section --

25 A. Okay. Yes.

1 Q. -- you see there is a part here about having kidney  
2 problems and taking certain medications, right?

3 A. Correct.

4 Q. And the only two medications they list are dronedarone,  
5 which is called Multaq, and ketoconazole tablets, which is  
6 called Nizoral, right?

7 A. Correct.

8 Q. Are those P-gp inhibitors?

9 A. No.

10 They are.

11 Q. It's hard to know what's a P-gp inhibitor, isn't it,  
12 Doctor, if they don't tell you?

13 A. These two medications are extraordinarily uncommonly used  
14 in medicine. That's very different than carvedilol.

15 And I would like to also point out, since you're pointing  
16 this point out, if you go down further on the page, it does  
17 state to share all of your medications with your physician.

18 Q. Ma'am, Multaq is used to help patients who have irregular  
19 heartbeats, right?

20 A. Yes.

21 Q. Are you telling the jury that patients with atrial  
22 fibrillation don't commonly take Multaq?

23 A. I'm telling you it's not a very commonly used medication  
24 in general.

25 Q. Okay. Well, let's get this straight.



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1 Those are P-gp inhibitors, aren't they?

2 A. Yeah.

3 Q. Even you, an expert in this case hired by BI, didn't know  
4 that just a second ago.

5 A. I -- so, excuse me, I said they were.

6 Q. First you said they weren't.

7 A. Yes, I did.

8 Q. Okay. All right.

9 If we can go back to the Medication Guide. Has the  
10 Medication Guide, patient Medication Guide ever included a  
11 statement or any information telling -- saying that you can't  
12 reverse Pradaxa, there is no antidote or reversal agent for  
13 Pradaxa?

14 A. No.

15 Q. Has the patient Medication Guide ever said patients who  
16 take Pradaxa are more likely to have a GI bleed than patients  
17 who take warfarin?

18 A. No.

19 Q. Okay. This information, basically what we just talked  
20 about, right?

21 You were hired by Boehringer to give opinions in this case  
22 really about whether they warned properly and what happened  
23 with the bleed, right?

24 A. That's correct.

25 Q. Has Boehringer or their counsel provided you anything --

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1 Medication Guide, television ad, magazine ad, a letter to  
2 patients, anything -- showing that they ever provided this  
3 information to patients directly?

4 A. Not directly in those words.

5 But they have -- I mean, again, they tell you not to take  
6 a combination of medications. So, No. 3, don't take Pradaxa  
7 and Coreg, I mean, this is something they're going to share  
8 with their physicians, but it does not say it directly.

9 It does say that they are more likely to have bleeding.

10 Q. What does?

11 A. The patient guide.

12 Q. It says they're --

13 A. It gives them risk factors --

14 Q. Excuse me.

15 Does it say they are more likely to have a GI bleed on  
16 Pradaxa than on warfarin?

17 A. No.

18 Q. Okay. So my question to you was -- set the Medication  
19 Guide aside.

20 A. Okay.

21 Q. Have you been provided anything by the counsel who hired  
22 you, who is representing Boehringer, that shows any of these  
23 issues, items, warnings, whatever you want to call them, have  
24 ever been communicated directly to patients like Betty Knight?

25 A. No.

1 MR. CHILDERS: Thank you.

2 (Plaintiffs' counsel conferring.)

3 MR. CHILDERS: That's all the questions I have, Your  
4 Honor.

5 THE COURT: All right. Redirect?

6 MR. LEWIS: I do. Do we want to give a couple minute  
7 stretch break?

8 THE COURT: Yes. Would you like to stand up and  
9 stretch for a minute, use the restroom?

10 We'll take a short break for that purpose. As soon as  
11 you're ready, come back out, and we'll get started.

12 (Recess taken from 4:53 to 5:02 p.m.)

13 (Jury not present.)

14 THE COURT: Mr. Lewis, how long do you expect?

15 MR. LEWIS: I'm hoping 20 minutes.

16 THE COURT: Okay.

17 MR. LEWIS: We really need to get this witness  
18 finished today.

19 THE COURT: Well, yeah, we'd like to, too.

20 What's your best guess about Dr. Crossley tomorrow?

21 MR. LEWIS: I mean, he has to be done tomorrow.

22 MS. JONES: He has to leave town by the end of the day  
23 because he has patients on Wednesday.

24 I intend to streamline his examination in light of --

25 THE COURT: If he wants to leave early, I betcha

1 they'll chip in on --

2 MS. JONES: I will communicate that option.

3 THE COURT: Honestly, given this, is this the witness  
4 that you thought would be shorter than Crossley or --

5 MR. LEWIS: Kind of.

6 THE COURT: So what I am getting at is we are probably  
7 going to be all day tomorrow on Crossley, even though we do  
8 have to finish.

9 MS. JONES: I was going to say, I suspect the direct  
10 with Dr. Crossley will be a little shorter because Dr. Shami  
11 covered some things we won't need to recover.

12 So --

13 THE COURT: Well, best guess.

14 All right. So you all now have copies of the  
15 instructions. Obviously we are going to have to wait awhile  
16 to talk about that.

17 MR. MOSKOW: Does this reflect the discussions we had  
18 on Friday or is this just a --

19 THE COURT: Yes.

20 MR. MOSKOW: Or Thursday. Okay.

21 THE COURT: What I tried to do is I made notes, and  
22 what I did was make some changes based upon the conference  
23 that we had.

24 MR. MOSKOW: Okay.

25 THE COURT: Okay. Let's bring the jury in.

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1 THE COURT SECURITY OFFICER: Yes, sir.

2 (Jury present.)

3 THE COURT: All right. We're going to do our best to  
4 finish this in the next half hour or so. All right?

5 Go ahead.

6 MR. LEWIS: Thank you. May it please the Court.  
7 Members of the jury, thank you for your patience.

8 Dr. Shami especially, thank you for your patience this  
9 afternoon. I will try to be brief and cover just a few topics  
10 that were covered during your cross-examination.

11 REDIRECT EXAMINATION

12 BY MR. LEWIS:

13 Q. The first topic that I would like to cover is Exhibit 86.  
14 You were asked several questions about what was in the  
15 physician label at various points in time. This question  
16 relates to aPTT tests.

17 This is a label that you were asked about from March of  
18 2011, to orient everybody, before Mrs. Knight had Pradaxa  
19 prescribed to her by her physician. And if we go to page 5 of  
20 this label, we see at the top something about aPTT.

21 The thing that was being complained about during your  
22 cross-examination is addressed in this physician label; is it  
23 not?

24 MR. CHILDERS: Objection, leading, Your Honor.

25 MR. LEWIS: Let me rephrase that.

1 THE COURT: Please.

2 BY MR. LEWIS:

3 Q. Dr. Shami, does Boehringer discuss aPTT tests in the label  
4 for March of 2011?

5 A. It looks like, yes. Yes. A recommended therapeutic dose  
6 of dabigatran prolongs the aPTT, ECT and TT test.

7 Q. What does -- as a doctor, what does that mean when you  
8 read dabigatran prolongs aPTT?

9 A. That means that you are more likely -- I mean, you're  
10 anticoagulated. That's exactly what it means.

11 Q. It means you're going to get higher scores --

12 A. Right.

13 Q. -- on the aPTT test.

14 A. I mean --

15 Q. Is that how you understand it?

16 A. Yeah.

17 MR. LEWIS: I'm finished with that exhibit. Thank  
18 you.

19 You were asked all kinds of questions about the  
20 label after -- the label changes after Dr. MacFarland  
21 prescribed to Mrs. Knight Pradaxa for the first time in  
22 October of 2011.

23 Q. Do you recall those questions?

24 A. Yes.

25 Q. And just to orient everybody, Dr. MacFarland did not

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1 prescribe Pradaxa in 2013 when she got the bleed; is that  
2 right?

3 A. That is correct.

4 Q. Okay. But Exhibit 5980, which is in evidence, is the  
5 label from November of 2011. One month after Dr. MacFarland  
6 first prescribed Pradaxa, the label in 2011, November of 2011  
7 was changed.

8 Do you remember reviewing that?

9 A. Yes.

10 Q. And for any doctor, whoever reviewed and was going to  
11 prescribe Pradaxa to a patient after November of 2011, do you  
12 think they should have reviewed the label just based on your  
13 practice?

14 A. Yes. We review the label intermittently, yes.

15 Q. Do you think in that 18-month time frame after Dr.  
16 MacFarland first prescribed Pradaxa, that maybe she should  
17 have reviewed the label?

18 A. Yes, and she may have reviewed the label.

19 Q. And nonetheless, two years later when other physicians are  
20 prescribing Pradaxa, would you have expected them to have  
21 reviewed the label back then?

22 A. Yes.

23 Q. Okay. So November of 2011, in Drug Interactions, we see  
24 on the third bullet point: P-gp inhibitors in patients with  
25 severe renal impairment, Pradaxa use not recommended.

1 That was in the label as of November of 2011; is that  
2 fair?

3 A. That is correct.

4 Q. If we back out of that, and we go to page 6 under Table 3.

5 Here we are again, November of 2011, what does it say  
6 right under Table 3?

7 A. It gives you the percentage increase that the drug  
8 increases the -- yeah.

9 Q. Table 3 indicates the relative increase for folks who have  
10 renal impairment; is that right?

11 A. That is correct.

12 Q. But let me read the sentence underneath the table:  
13 Patients with severe renal impairment were not studied in  
14 RE-LY. So let me ask you about that.

15 Does it appear from the November 2011 label that  
16 Boehringer has hiding the fact that patients with severe renal  
17 impairment were not studied in RE-LY?

18 A. No.

19 Q. Is this a document that is referred to in the Medication  
20 Guide as something that could be available to patients?

21 A. Yes.

22 MR. LEWIS: I'm finished with that exhibit. Thank  
23 you.

24 Are you able to pull up Exhibit 3124 that was referred  
25 to? It was a document, the Eikelboom paper.



1 Q. Just real briefly, this is a paper that you did review as  
2 part of your work in the case; is that correct?

3 A. That's correct.

4 Q. Okay. You weren't asked about certain portions of this  
5 paper. You were only asked about one piece of it, and so I  
6 want to sort of reference point us to 3124, page 6, please.

7 And that first full paragraph, that first sentence, what  
8 does that say?

9 A. Intracranial bleeding remains one of the most feared  
10 complications of anticoagulant therapy.

11 And --

12 Q. What does that mean to you?

13 A. That means that if somebody has a -- I mean, there are no  
14 anticoagulation -- it's very hard to reverse somebody who has  
15 a bleed in their head, so it's a very concerning thing.  
16 People can die. Even a harder scenario is when people can't  
17 walk, they can't talk. So it just means that it's a morbid --  
18 it's a complication we don't want.

19 Q. Now, Mr. Childers said, well, you don't treat brain  
20 bleeds.

21 Does that mean that it's any less important to you?

22 A. No, and I think I mentioned that to him.

23 Q. Okay. And you also mentioned the data that is reflected  
24 in this paper about the difference in reduction of stroke risk  
25 between warfarin and Pradaxa, right?

1 A. Yes.

2 Q. How is that important to your analysis?

3 A. I mean, again, when you are doing a risk-benefit ratio,  
4 you know, we can treat GI bleeding promptly. You know,  
5 strokes are very hard to reverse. Bleeds in the head, there  
6 is very little you can do. And yes, Mr. Childers was right, I  
7 do not directly treat them, but I've seen people who have had  
8 strokes and who have emboli, and it's not a scenario that you  
9 want for a family member.

10 So oftentimes when we're making these decisions, we almost  
11 have to juggle and say, you know, which one is worse? Is it  
12 the GI bleed or the -- you know, or any bleed or a stroke? I  
13 mean, it's a very difficult decision, as you saw that his  
14 physicians -- her physicians struggled with.

15 Q. When you're prescribing a medication, Doctor, is it fair  
16 to say that you take into account all of the potential risks?

17 A. Absolutely. I mean -- I mean, most of them, yeah. All of  
18 the ones that we think are relevant to the patient,  
19 absolutely.

20 Q. Now, this paper, Exhibit 3124, was published in May of  
21 2011, if we look at the circulation at the top of the very  
22 page we're looking at.

23 A. Okay. Yes.

24 Q. Maybe go to the next page, please. You see it was  
25 circulated May 31st of 2011.

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1 Are you aware that Boehringer funded this study and the  
2 publication of this paper?

3 A. Yes.

4 Q. And in this paper, there's a description of the lower risk  
5 of stroke with Pradaxa versus warfarin; is that right?

6 A. That is correct.

7 Q. And there is a description of a lower risk of brain bleed  
8 with Pradaxa versus warfarin; is that right?

9 A. That is correct.

10 Q. And there is a description of a higher risk of  
11 gastrointestinal bleed with Pradaxa versus warfarin, right?

12 A. That's correct.

13 Q. And is it fair that a physician prescribing Pradaxa or  
14 considering Pradaxa versus warfarin consider all of those  
15 factors?

16 A. Yes, absolutely.

17 Q. Not just gastrointestinal bleed?

18 A. Yes.

19 MR. LEWIS: I'm finished with that exhibit.

20 Now I want to ask you back about some of the documents  
21 that were covered by Mr. Childers related to Mrs. Knight.  
22 There was a lot of discussion about whether or not the papers  
23 said that Mrs. Knight had a bleed on warfarin in 2008, so I'm  
24 going to get to that in a second.

25 But based on the INR readings alone that you saw and

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1 reviewed in this case, Mr. Childers asked you about that first  
2 question I asked you, is warfarin safe and effective for Mrs.  
3 Knight.

4 Q. Just based on those INR readings alone, what is your  
5 opinion on that?

6 A. No, and that's what I was telling him.

7 You know, there was an implication that we misrepresented  
8 it, but we were just calculating the number of times the INR  
9 was above and then the number of times it was below. It was  
10 completely an accurate calculation.

11 Q. And you were asked about, I believe, Exhibit 9005A-27. It  
12 may have been a different record that was referenced.

13 But I remember this specifically when Mr. Childers was  
14 commenting that she appears to be on all three medications at  
15 this time.

16 A. I actually think that is incorrect.

17 Q. Well, let's just look at what the assessment plan says.

18 A. Yeah.

19 Q. So regardless of whether she's on all three medications at  
20 this time or not --

21 A. Right.

22 Q. -- let's look at 9005A, page 27 towards the bottom.

23 A. Right.

24 Q. He didn't show you this part, so I want to make sure the  
25 jury gets a full view of the very record that Mr. Childers was

1 relying on here.

2 What does Dr. Gunnalaugsson said about whether or not Mrs.  
3 Knight can be on all three medications?

4 A. Unfortunately I don't think she can take coumadin, aspirin  
5 and Plavix. I think that she can stop the Plavix now.

6 Q. That's what it says?

7 A. Yeah.

8 Q. You were also asked --

9 MR. LEWIS: I'm finished with that exhibit. Thank  
10 you.

11 You were also asked a number of questions about the  
12 switch from warfarin to Pradaxa in October of 2011 --

13 THE WITNESS: That is correct.

14 MR. LEWIS: -- and the discussion about whether or not  
15 any record reflects that there was a reason for the switch  
16 other than seeing a TV ad or request by the family.

17 Q. Do you remember those questions?

18 A. Yes, I do.

19 Q. Have you seen records to suggest otherwise?

20 A. Yes.

21 Q. You referenced one of the records was the form that Dr.  
22 MacFarland filled out?

23 A. That is correct.

24 Q. Okay. But I also want to refer to 9009A-425.

25 Do you recognize this as a handwritten note from a visit

1 around October 17th of 2011?

2 A. Yes. It says: I want to replace coumadin with a new  
3 medication.

4 Q. And that looks like maybe that was a request since it is  
5 under the chief complaint. That is somebody saying something  
6 to the doctor?

7 A. That is correct.

8 Q. But let's go down a little further to the bottom left-hand  
9 corner where it says Diagnosis.

10 A. Uh-huh.

11 Atrial fibrillation, supratherapeutic coumadin.

12 Q. What does that mean to you as far as a diagnosis?

13 A. I mean, again, it implies that her levels aren't within  
14 that 2 to 3 INR range, and that it's -- you know, again, it's  
15 more evidence that it's a difficult drug for her to keep  
16 therapeutic.

17 Q. Now, you were asked about the 2008 potential or suspected  
18 bleed, and so I just want to get a couple things --

19 A. Sure.

20 Q. -- out of the way there.

21 Definitely no question about it, a colonoscopy was not  
22 done in 2008, correct?

23 A. That is correct.

24 Q. Okay. Is it fair to say you can't rule in that there was  
25 a bleed without -- without that possibly?

1 A. That is correct.

2 Q. Okay. Is it also fair to say you can't rule it out  
3 without a colonoscopy?

4 A. She -- you mean in November 2008?

5 Q. Yes.

6 A. She had a bleed. I mean, there is no question in my mind  
7 she had a bleed. She had a hemoglobin drop. She had dark  
8 stools. Any gastroenterologist will tell you she's having a  
9 bleed.

10 Dr. Rohrbach didn't just get consulted for another reason,  
11 he got consulted for GI bleeding. I mean, that is -- it may  
12 not say it in the records, but that is the reason he got -- I  
13 mean, he didn't just get consulted to get consulted. He  
14 didn't get consulted for anemia. She's been anemic for a long  
15 period of time. So he got consulted to work up the blood  
16 loss, and so he did work it up.

17 Q. And were there references in the record after that date to  
18 physicians who commented that she had a GI bleed?

19 A. There were, and I think we had discussed several of them,  
20 including her cardiologist.

21 Q. Okay. Final point.

22 You were asked a lot of questions about what Dr.  
23 Abdelgaber said --

24 A. Yes.

25 Q. -- what he said in his deposition, what he said in his

1 records.

2 Do you still have the page that Mr. Childers showed you of  
3 his deposition? It was like one page.

4 A. I'm sure I do. I have it.

5 Q. You have it in front of you?

6 A. I do.

7 Q. The question that he stopped on was: Did you feel at any  
8 time during her admission that her life was in danger from the  
9 GI bleed?

10 And Dr. Abdelgaber said: That's why I admitted her to the  
11 hospital.

12 Do you see that is the page he gave you?

13 A. Correct.

14 Q. There's more to the question and answer after that, isn't  
15 there?

16 A. Yes, I'm sure there is.

17 Q. On this very page --

18 A. Did you expect that she would be able to be treated for  
19 her GI bleed? That was the plan.

20 Q. And the question is: And that's how it turned out.

21 And the answer was?

22 A. Yes.

23 Q. Did, in fact, Mrs. Knight -- regardless of the severity of  
24 the bleed when she had it, was it treated correctly?

25 A. She was treated correctly.



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1 Q. You were also asked some questions about whether Dr.  
2 Abdelgaber felt that she didn't bounce back after May of 2013.  
3 And I can show you this if you want to refresh your  
4 recollection.

5 But you recall he was asked a lot of questions even after  
6 that particular question that was referred to you, including:  
7 It's just as likely, isn't it, that her deterioration began  
8 with the heart attack and the placement of the stents in April  
9 of 2013?

10 And Dr. Abdelgaber said: Possibly correct.

11 Do you recall that testimony?

12 A. Yes.

13 Q. But let's not go back and forth on depo testimony, medical  
14 records. Let's go to 9001 and here where I ended the direct  
15 examination.

16 If we're going to talk about Dr. Abdelgaber's credibility,  
17 should we talk about this document 9001?

18 Is that signed by Dr. Abdelgaber?

19 A. Yes, it is.

20 Q. And that is signed on 9/4/2013?

21 A. That is correct.

22 Q. Two days after Mrs. Knight passed.

23 Dr. Abdelgaber could have put anything in this document  
24 that he felt was related to her passing; is that fair?

25 A. Yes, that is fair.

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1 Q. In fact, he was obligated to do that under the law.

2 Do you understand that is a death certificate?

3 A. I do.

4 Q. Okay. And this document that Mr. Childers has avoided  
5 throughout this trial doesn't indicate anything about --

6 MR. CHILDERS: Objection, Your Honor.

7 THE COURT: Sustained. That is an argumentative  
8 statement about what counsel did. Ignore the statement about  
9 Mr. Childers' use of this document.

10 MR. LEWIS: Fair enough. Fair enough.

11 Q. Does Exhibit 9001 in any place written by Dr. Abdelgaber  
12 indicate that a GI bleed or Pradaxa was responsible for Mrs.  
13 Knight's passing?

14 A. No.

15 MR. LEWIS: Okay. That's all I have, Your Honor.

16 THE COURT: All right. Recross?

17 MR. CHILDERS: Yes, Your Honor.

18 RECROSS-EXAMINATION

19 BY MR. CHILDERS:

20 Q. Doctor, you understand, we sat down and talked with Dr.  
21 Abdelgaber --

22 THE COURT: Turn your microphone on.

23 MR. CHILDERS: Hello?

24 THE COURT: There it is.

25 MR. CHILDERS: Sorry.

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- 1 Q. You understand that, right? That's what a deposition is.
- 2 A. Correct.
- 3 Q. You were deposed. We asked you a lot of questions that
- 4 you didn't write down in your report, correct?
- 5 A. Yeah.
- 6 Q. And so we got to ask Dr. Abdelgaber himself to tell the
- 7 jury what he thought as far as her debility, Betty Knight's
- 8 debility after her May 2013 bleed --
- 9 A. Correct.
- 10 Q. -- whether or not she ever recovered, and how she did
- 11 after that, right?
- 12 A. Yes.
- 13 Q. So instead of just writing few words on a piece of paper,
- 14 he actually told the jury this is what I believe, right?
- 15 A. Okay.
- 16 Q. He said that, right?
- 17 When you say okay, it's not a yes or no, so I need you to
- 18 answer yes or no.
- 19 A. If you're saying he said it, yes.
- 20 Q. You read his deposition.
- 21 Do we need to go over it again?
- 22 A. I -- I do not read every single -- I mean, I can't recall
- 23 every single word out of every deposition. But I'm agreeing
- 24 with you.
- 25 Q. Okay. And when you read his deposition, you saw that he

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1 said that she never recovered like he had hoped from the GI  
2 bleed, correct?

3 A. I saw that.

4 Q. And you told the jury that you don't disagree with him,  
5 correct?

6 A. I can't -- I can't disagree with him. I mean, that's what  
7 he said, so --

8 Q. What he said was Betty didn't seem to ever get better or  
9 bounce back from the May 2013 GI bleed, right?

10 A. I don't think Ms. Knight was -- she was chronically ill  
11 since 2008. But I'm not going to argue with him on that  
12 statement, that is true.

13 Q. In fact, you told me and you told the jury a little while  
14 ago you defer to Dr. Abdelgaber's opinion on that, right?

15 A. That's his opinion, that's correct.

16 Q. He's the doctor who treated Mrs. Knight, right?

17 A. Yeah.

18 One thing I want to point out is he's only known her since  
19 April. He's seen her once outside of the hospital. So his  
20 ability to say whether she bounced back or not is a little  
21 bit, in my opinion, questionable because he has not followed  
22 her entire course. He was a new primary care physician.

23 Q. You understand we took his deposition after she had died,  
24 right?

25 A. Yes.

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1 Q. And he had a chance to review medical records, correct?

2 A. He did.

3 Q. And then after he reviewed the medical records and treated  
4 Mrs. Knight, he said she didn't ever seem to get better or  
5 bounce back from the May 2013 bleed, right?

6 A. So that statement is based on reviewing medical records, I  
7 just want to make that clear. That is different than saying  
8 he saw her firsthand and determined that, correct? It's two  
9 different things.

10 Q. He did see her in that interim period, didn't he?

11 A. He saw her a few times, correct.

12 Q. Okay. So not only did he read the records, he saw Betty  
13 Knight himself, right?

14 A. Correct.

15 Q. Okay. And when he did that, when he thought about all of  
16 that information, his testimony that the jury heard was she  
17 didn't seem to get better or bounce back from the May 2013  
18 bleed, right?

19 A. That's what his testimony is, correct.

20 Q. And your testimony is you defer to him for that opinion,  
21 right?

22 A. I mean, again, my testimony is that she is chronically  
23 ill. But I do defer to him on that point, that's fine.

24 Q. All right. Ma'am, I hate to do this again, but we're  
25 going to have to look at your deposition.

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1 MR. LEWIS: She answered the question, Your Honor.

2 This isn't impeachment.

3 THE WITNESS: I'm answering it, yeah.

4 THE COURT: Well, I do think it's been asked and  
5 answered a number of times. You've pointed out the deposition  
6 testimony. So --

7 MR. CHILDERS: Fair enough, Judge.

8 Q. I want to ask you about this progress note.

9 Remember this one?

10 A. I do.

11 Q. Okay. And you just talked about it with Mr. Lewis, right?

12 A. Yes.

13 Q. And somehow you and Mr. Lewis took from this document that  
14 Betty Knight was not on coumadin and Plavix and aspirin at the  
15 same time?

16 A. She was. She was on triple therapy in March.

17 Q. Okay. Maybe I'm confused.

18 I thought he got up and said, isn't it true she never was  
19 on all three of those drugs together, and that I got it  
20 wrong --

21 A. He did not say that.

22 Q. Okay. I just want to make sure the jury understands --

23 A. He didn't -- I don't recall you saying that.

24 MR. LEWIS: This is improper examination. First of  
25 all, I didn't say that, but this is improperly suggesting to

1 the jury what I said and didn't say.

2 THE COURT: Well, as I understand it, he's trying to  
3 recount what he believed to be redirect. But the witness has  
4 clarified it, so --

5 MR. CHILDERS: Thank you, Your Honor.

6 THE COURT: -- move on.

7 BY MR. CHILDERS:

8 Q. No question, Betty Knight was on coumadin, Plavix and  
9 aspirin at the same time when this record was created in March  
10 of 2009, right?

11 A. Correct.

12 Q. She didn't have a bleed in March of 2009, did she?

13 A. No, she did not.

14 Q. In fact, from the records you saw, she didn't have any  
15 bleed during the time, the entire time she was on coumadin,  
16 Plavix and aspirin together, right?

17 A. That is correct. But if you go further down the note,  
18 which you don't point out, they say she should come off  
19 sometime --

20 Q. Well, let's --

21 A. -- in March.

22 Q. Right.

23 That was the back page where for some reason --

24 A. I don't think she can take coumadin, aspirin and Plavix.

25 Q. Based upon nothing in this actual record telling us why

1 that is, right?

2 A. It states it.

3 Q. Okay. But at the time, she's on all three of them, right?

4 A. Yes.

5 Q. Not having a bleed, right?

6 A. Not at this time, no.

7 Q. Okay. I'm not sure why you were asked about intracranial  
8 hemorrhage, but I just have to follow up with you.

9 You relied on the paper that was written by Dr. Reilly  
10 about outcomes that relate to how much Pradaxa is in a  
11 patient's blood --

12 A. Correct.

13 Q. -- right?

14 And I think you told the jury, hey, with Pradaxa, we get a  
15 lot less intracranial hemorrhage, right?

16 A. Yeah. Again, on the studies, it --

17 Q. Okay.

18 A. Based on RE-LY.

19 Q. Based on RE-LY where no 75-milligram dose was ever tested,  
20 right?

21 A. No.

22 Q. Where no severe renal patients were included, right?

23 A. That's correct. It was moderate renal insufficiency in  
24 that one.

25 Q. And so you don't know, and you can't tell the jury that a



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1 75-milligram dose of Pradaxa is any better when it comes to  
2 intracranial hemorrhage than warfarin, can you?

3 A. I can't tell you specifically with the 75, correct.

4 Q. And that's what Ms. Knight took, right?

5 A. She did.

6 But, again, I don't think you can use that 75 dose as not  
7 being -- you're extrapolating to GI bleeding 75 being too much  
8 for her, and she has an increased risk of GI bleeding. Yet on  
9 the other hand, Mr. Childers, you're saying that it's not  
10 going to benefit her in terms of strokes and intracranial  
11 bleeding. So it's kind of, I don't know, an unusual  
12 situation.

13 Q. I'm not the one who decided to never test the 75-milligram  
14 dose against warfarin, am I?

15 MR. LEWIS: Your Honor, that's argumentative.

16 THE COURT: I agree.

17 MR. CHILDERS: Okay.

18 Q. The choice as to whether or not to actually run a clinical  
19 trial with the 75-milligram dose to see if it performed better  
20 than warfarin, that choice has never been actually exercised  
21 by the company, right?

22 A. Nor has the FDA requested that information.

23 Q. That's not my question.

24 You told us right now you don't know if the 75-milligram  
25 dose is better than warfarin or not, right? You don't have

1 clinical data on that.

2 A. For what specific thing? I'm sorry.

3 Q. For anything.

4 A. Now we're -- I mean, again, it's a modeling study, and you  
5 are extrapolating from it.

6 Q. Okay.

7 A. So if it was better for the 150 and the 110, you're saying  
8 the plasma levels are increased in her, I mean, I don't -- I  
9 don't see why you couldn't extrapolate that.

10 Q. There's never been a clinical trial to prove that, has  
11 there?

12 A. That is correct.

13 Q. Okay. So you can't tell the jury that in real patients,  
14 not fake computer model patients, that the 75-milligram dose  
15 is better, worse or the same as warfarin in preventing  
16 strokes, correct?

17 A. That is correct.

18 Q. And you can't say whether the 75-milligram dose is better,  
19 worse or the same as warfarin for anything, including  
20 intracranial hemorrhage, right?

21 A. Well, again, we are extrapolating.

22 Q. Okay. I just want to ask you again about the label when  
23 Ms. Knight started Pradaxa.

24 You agree with me -- I think it was Exhibit 86 that's in  
25 front of you. It did not have that language about severe

1 renal patients not being in a clinical trial in Table 3,  
2 right?

3 A. Yeah. This is that old label?

4 Q. This is the label when she started taking Pradaxa.

5 A. Okay. Yes, it doesn't have it on there.

6 Q. And --

7 A. And a few months later, it does.

8 Q. Right.

9 And when that language was added --

10 A. Uh-huh.

11 Q. So let me back that up.

12 So when Mrs. Knight starting Pradaxa, that information not  
13 only wasn't available to her, it wasn't available to her  
14 doctor either, right?

15 A. It's not there.

16 Q. Okay. So when she went and filled her first prescription,  
17 that information never would have gotten to her whether it was  
18 through the label, through her doctor or through the  
19 Medication Guide, correct?

20 A. That is correct. With the first few prescriptions,  
21 correct.

22 Q. And when the label was actually changed to add that  
23 information, Boehringer never sent a dear doctor letter or any  
24 other written communication that you've ever seen to Dr.  
25 MacFarland or any other doctor telling them about that change,

1 right?

2 A. That is correct.

3 Q. And they never -- Boehringer never sent any information  
4 directly to Betty Knight or any other patient about that  
5 change in the label, correct?

6 A. That is correct. But the label is available for  
7 physicians to review. And like I said, it's standard of care  
8 for us to re-review labels.

9 And additionally, Mr. Childers, there were more than  
10 one -- there was more than one physician prescribing it. So  
11 would you -- I mean, if somebody is going to renew the drug,  
12 especially right before a GI bleed, they probably would have  
13 reviewed the label.

14 Q. And you read that record that she stopped taking Pradaxa  
15 because she had to have stents put in, just like the time back  
16 in 2008 when she stopped taking coumadin, right?

17 A. That's correct.

18 Q. And then when you get done with whatever procedure, they  
19 just -- and the words were restart, right, on Pradaxa?

20 That's what it says in the label?

21 A. Correct.

22 Q. I'm sorry. In the medical record?

23 A. In the medical record, yes.

24 Q. All right. So this wasn't some new doctor who said I  
25 gotta figure out what this lady needs for atrial fibrillation.

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1 It was the doctor at the hospital who said, she came in on  
2 Pradaxa, let's put her back on Pradaxa because now the surgery  
3 is over, right?

4 A. Right.

5 Q. Okay. Do you read the drug label every single time that  
6 you write a prescription?

7 A. No. But if I'm -- if I'm covering or if there is a new --  
8 I will -- I will glance through, absolutely.

9 Q. You don't do that every time you write a prescription,  
10 right?

11 A. Not every time I write a prescription, no. I'm usually  
12 familiar with the labels of the prescriptions I write. But  
13 yes.

14 Q. When the labels change, oftentimes the drug company sends  
15 you a letter to tell you we made a change to the label, right?

16 A. Sometimes they do, and sometimes they don't, you're  
17 correct.

18 Q. And when they send you those letters, you are more likely  
19 to see the change that got made, aren't you?

20 If you read the letter.

21 A. I don't -- yeah, if you read the letter. We get inundated  
22 with mail.

23 Q. There is so much information you have to know, you need  
24 somebody to prompt you to know something like that, don't you?

25 A. It's actually something, like I said, we do habitually.

1 We re-review labels. That's something we do.

2 MR. CHILDERS: That's all the questions I have.

3 THE COURT: All right. Any other questions?

4 MR. LEWIS: No, Your Honor.

5 THE COURT: All right. Thank you, Doctor.

6 THE WITNESS: Thank you. I appreciate it.

7 THE COURT: You may be excused.

8 Was this your notebook, Mr. Lewis?

9 MR. LEWIS: Yes.

10 THE COURT: All right.

11 All right. Ladies and Gentlemen, you've heard all of  
12 the evidence you'll hear today. In that last break, I talked  
13 with the lawyers some about what remains to be done.

14 The plaintiffs -- or, rather, the defendant does have  
15 one more expert. He is here, he is ready to start testifying,  
16 but we're not going to do that today for obvious reasons. He  
17 will be testifying first thing in the morning. So we're going  
18 to adjourn until 9:00 a.m. tomorrow. The defense will call  
19 that witness.

20 No one is quite sure in terms of counsel how long that  
21 will take. My guess is it will take most of the day. Given  
22 that, I'd say it's very likely that you'll have to come back  
23 here on Wednesday. It may be that we will finish the  
24 testimony tomorrow, and it's certainly possible, maybe even  
25 probable that we won't have time for much other than that.

1           Once we finish the testimony, of course, from the  
2 defense, the plaintiff has a right to introduce rebuttal  
3 evidence. Usually that is pretty limited, if at all.

4           The instructions are being worked on. We worked on it  
5 on those days when you weren't here. We've still got some  
6 more work to do, so I'm going to make sure that our work on  
7 the instructions doesn't interfere with or interrupt your  
8 getting the evidence and being prepared to start deliberating.  
9 But I can tell you that the instructions, as you can imagine,  
10 will take awhile to read.

11           Then we will have closing statements. In a  
12 complicated trial lasting several days, I'm going to give the  
13 lawyers sufficient agreeable time to make their arguments. So  
14 my guess is that we'll take up probably most or all of  
15 tomorrow with the last evidence, and then come back on  
16 Wednesday for instructions and closing arguments, and then you  
17 will get the case.

18           So with that, I want to remind you of my previous  
19 instructions from last week. Don't deliberate. Don't start  
20 looking into anything about the case. Don't discuss it with  
21 anyone. We appreciate you persevering today. It was a long  
22 day. Remember to leave your notes here.

23           And with that, you're excused until tomorrow morning  
24 at 9:00 a.m.

25           Could I see counsel just at side bar?

1 Doctor, you're excused.

2 THE WITNESS: Okay. Thank you.

3 THE COURT: Everybody else should remain in the  
4 courtroom until all of the jurors have departed.

5 (Side bar conference, not reported.)

6 (Jury not present.)

7 THE COURT: All right. Do you have the Court's  
8 proposed instructions?

9 MR. MOSKOW: Yes, Your Honor.

10 THE COURT: So, first, I'm just going to walk through  
11 it.

12 Unfortunately, in preparing this, we didn't realize  
13 until Blake was doing it that the computer automatically  
14 changed the instruction number. I had tried to do it so that  
15 your original numbers stuck with it, because I moved some  
16 paragraphs around. So they might be in places that are not  
17 where you thought, and they would bear a different number, but  
18 I think I can explain it to you.

19 So we can quickly go through the first instructions  
20 all the way through -- I'll point out instruction No. 4 is  
21 just the standard explanation of who an expert is and how the  
22 jury is entitled to consider them.

23 Instruction 5 deals with people who testify by  
24 deposition.

25 6 explains the burden of proof. And I know that you



1 all were arguing about may or must. I don't see much merit to  
2 either one over the other, but the West Virginia pattern  
3 instruction uses may, so I'm sticking with that since these  
4 are state law claims.

5 7 and 8 were language that you all had apparently  
6 already agreed upon.

7 Then paragraph 9 starts the plaintiffs' claims. I  
8 generally used what I understood the parties to have agreed to  
9 when we -- let me find where I marked up from our discussion.

10 Maybe this is a good time to discuss what counsel  
11 mentioned briefly to me, and that is where there is mention of  
12 the causation issue. There is causation and proximate cause,  
13 and what I tried -- what I understood was, first, that  
14 plaintiffs' injury claims consist of two types. One is Betty  
15 Knight's personal injury because she had a bleed in April and  
16 suffered until her death. And then, secondly, the wrongful  
17 death damages, which include the general damages for the  
18 survivors of her estate.

19 And so I tried to simply state that by saying that  
20 plaintiffs claim that Pradaxa proximately caused her personal  
21 injuries and may have caused or contributed to her death. And  
22 then the rest really seemed to me to be consistent with what  
23 you all submitted.

24 So what exactly are you concerned about there?

25 MR. MOSKOW: Thank you, Your Honor.

1 I think maybe if we start down a little bit further in  
2 the instruction where it says BI denies, and denies that any  
3 wrongful conduct by BI caused any injuries to Mrs. Knight or  
4 caused or contributed to her death, we believe that both there  
5 and at the top it should be contributed or caused her injuries  
6 and contributed or caused her death.

7 And it's particularly significant --

8 THE COURT: Well, you don't need to argue it.

9 I agree under the West Virginia law something doesn't  
10 have to be -- plaintiff doesn't have to prove that the  
11 wrongful conduct was the sole cause of injury. Whether it's  
12 death or just personal injury, it's always either caused or  
13 contributed to. And so one is I could simply insert that  
14 language. I want to hear from the defendants.

15 MS. JONES: Your Honor, thank you.

16 As I recall -- I'm just looking at my notes from our  
17 last discussion on this. I thought we had adjusted that first  
18 sentence in a way that everyone was agreeable to, to say was a  
19 proximate cause of her injuries, including her death.

20 The revised version seems to introduce a little bit of  
21 asymmetry inasmuch as it refers to proximately causing her  
22 injuries and proximately causing and contributing to her  
23 death. And I wasn't sure if there was a reason for that  
24 distinction, and I wonder a little bit if the jury seeing that  
25 will think there is something unique about the injury claim

1       versus the death claim.

2               THE COURT: Well, it was nothing nearly that  
3       purposeful in the Court's decision.

4               MS. JONES: Okay.

5               THE COURT: So are you comfortable with just inserting  
6       the phrase -- and I agree, and I even made note of this, but I  
7       didn't want to repeat this phrase throughout.

8               One option would be to simply say that plaintiff  
9       claims that Pradaxa injured Mrs. Knight and was a proximate  
10      cause of her injuries, including death.

11              MR. MOSKOW: As long as proximate cause is defined  
12      someplace in --

13              THE COURT: Well, the next instruction on the next  
14      page does define proximate cause.

15              MR. MOSKOW: So -- oh. They're moved a little bit in  
16      what we have.

17              THE COURT: Yes. So -- but on the draft I gave you  
18      just this afternoon, the instruction on page 12, it's labeled  
19      here instruction 28, so somehow this one managed to keep a  
20      different number, but it's the definition of proximate cause.

21              MS. JONES: As I understand it, Your Honor, what  
22      appears on page 12 is verbatim what plaintiffs had proposed on  
23      the definition of proximate cause.

24              THE COURT: I think that's right out of the pattern  
25      instruction.

1 MR. MOSKOW: We're fine with that, Your Honor. Our  
2 concern was if there is the word cause without contributed, it  
3 was a concern.

4 But just calling it proximate cause and having --

5 THE COURT: A proximate cause.

6 MR. MOSKOW: Okay.

7 THE COURT: All right. We'll make note of that and  
8 change it throughout. So that takes us through those.

9 Proposed instruction No. 6 entitled, by the defendant,  
10 necessity of expert testimony, I looked at these cases, and I  
11 agree with the defendant. I don't think you could have a  
12 failure to warn in a pharmaceutical product case without an  
13 expert, and it's the expert that has to establish that the  
14 warnings are inadequate.

15 MR. MOSKOW: We understand, Your Honor.

16 THE COURT: All right. So that will be that.

17 Next was the defendant's failure to test. There was  
18 an original version of that that included the statement that  
19 the plaintiff was not making any claim for failure to perform  
20 clinical testing, and I took that statement out.

21 MR. MOSKOW: That's fine with the plaintiffs, Your  
22 Honor.

23 THE COURT: All right.

24 Then I grouped --

25 MS. JONES: Your Honor, before we move on to failure

1 to test, I think what we had proposed was language that said  
2 more explicitly that when they were considering a failure to  
3 warn, that they could not consider a failure to warn about  
4 testing that was or was not done. That is -- I think that's  
5 just a variation that we had proposed.

6 And the reason that we had proposed that is because  
7 there has been so much discussion, including this afternoon,  
8 about testing and whether the company tested and whether BI  
9 had hired Dr. Shami to run a test, that I think it has to be  
10 quite explicit to the jury this isn't about whether or not the  
11 company tested or whether they warned enough about how they  
12 tested.

13 THE COURT: Okay. So I'm looking at page 6 of what  
14 you guys gave me Friday. And under failure to test -- this is  
15 all included under BI's proposed instruction No. 4 -- you have  
16 the first sentence, You have heard testimony. That remains in  
17 this latest draft.

18 The next sentence starts, Under law, BI cannot be held  
19 liable. That remains.

20 The third sentence that you had was: Further, BI  
21 cannot be held liable for failure to provide warnings on the  
22 clinical testing of Pradaxa. I struck that sentence.  
23 Plaintiffs had objected to that sentence, as I recall, and we  
24 talked about it. We'll come back to that in a minute.

25 And then I struck the very last sentence in the

1 defendant's original version that starts, The process of  
2 clinical testing performed, because that sentence just didn't  
3 make any sense to me.

4 MS. JONES: And consistent with Your Honor's  
5 direction, we had exchanged with plaintiffs' counsel over the  
6 weekend a proposal on an alternative to failure -- alternative  
7 instruction which we provided I think earlier this morning by  
8 e-mail, which I'm happy to have printed off if we don't have  
9 that printed already.

10 THE COURT: Well, I think that's what I was just  
11 reading from. This is what you gave Blake, and this is what  
12 he gave me, which --

13 MS. JONES: I thought -- I think we gave something  
14 that didn't have -- does that have a comment bubble on the  
15 side?

16 THE COURT: Yes, it does. It lists on the column,  
17 which is not on my draft -- lists in the right column and  
18 shaded plaintiffs object.

19 MS. JONES: So if I could, just for the record, Your  
20 Honor.

21 What we had proposed -- and I apologize, I'm reading  
22 this off of a device. You have heard testimony -- thank you.

23 You have heard testimony regarding the clinical  
24 testing of the 75-milligram dose of Pradaxa, which is  
25 consistent with what is in the current draft.

1 Under the law, BI cannot be held liable for a failure  
2 to perform clinical testing on Pradaxa, which is also in the  
3 draft.

4 Then we had proposed: BI also does not have an  
5 obligation to warn about the manner in which the 75-milligram  
6 dose of Pradaxa was tested. That is a sentence that varies.

7 And then the last sentence is, I think, basically  
8 consistent.

9 THE COURT: Okay. Now I see that.

10 MR. CHILDERS: I don't think that's an accurate  
11 statement of law. What they have an obligation to warn about  
12 is the drug, and so to say there's some particular area they  
13 don't have to warn about, there's no basis for that.

14 THE COURT: Well, this is a good point to raise the  
15 other facet of this discussion about the 75-milligram dose.

16 So, as I understand it, the facts are clear that when  
17 BI submitted the RE-LY study and sought approval of the drug,  
18 ultimately they obtained approval. As part of that approval  
19 process, the FDA considered, first, data that was submitted  
20 through RE-LY that clearly indicated that patients with severe  
21 renal impairments were not included in the study. Secondly,  
22 as I understand it, it was clear, and the FDA so stated, that  
23 the 75-milligram dose was based upon modeling, not upon  
24 patient testing.

25 So as I have continued to consider this federal

1 preemption argument, I fully intended to ask the parties to  
2 further argue about this. Because when I look at Wyeth and  
3 the other cases, it suggests to me that where the FDA  
4 explicitly approved the 75-milligram dose, with full knowledge  
5 that this was a dose developed by modeling and not by  
6 patients, and that in fact patients with severe renal problems  
7 as defined were not included in the study, if that is the  
8 case, I don't see how that is not a preempted decision as to  
9 that label, as to the initial label.

10 MR. CHILDERS: I would say because the facts of the  
11 case are they added that language to the label when they did a  
12 CBE change later. So clearly they were able to add it at a  
13 later point in time, and all we're saying is that should have  
14 been done before Ms. Knight ever took the medication.

15 THE COURT: Well, you know, I understand. I  
16 understood that as your argument all along. But frankly when  
17 I see the preemption argument laid out as they have and look  
18 at the cases, the fact that the company could later change the  
19 label doesn't mean that the first label is not preempted.

20 It seems to me that the first label is explicitly  
21 approved by the FDA in the two respects that you're  
22 criticizing it. And if that's the case, even if they approved  
23 it, improved or made stronger the warnings later, those two  
24 things are not part of that subsequent analysis.

25 MR. CHILDERS: I think I understand, Your Honor.



1 THE COURT: Okay.

2 MR. CHILDERS: So she didn't get prescribed Pradaxa  
3 for a whole year after the drug was approved. Therefore,  
4 there was a whole year period of time when the label could  
5 have been changed to add this information and, in fact, they  
6 changed it a month after she started taking it.

7 So we're not arguing the launch label should have had  
8 that in there. We're just showing it wasn't in there, and it  
9 didn't make it in there until after she started taking it.  
10 They could have made that CBE change at any point.

11 THE COURT: I agree.

12 My problem is still that it strikes me that you are  
13 claiming that that first label was inadequate. It constituted  
14 a failure to warn about the 75-milligram dose for the reason  
15 that the study did not include severely impaired renal  
16 patients, and the study did not include actual testing on  
17 people but, rather, the company and FDA relied upon modeling.

18 So those two things, it seems to me, were clearly  
19 known and part of the FDA approval. And if that is the case,  
20 then even if the company does later on change it, that doesn't  
21 make that label -- excuse me -- that label is still subject to  
22 the preemption analysis.

23 When I read these cases, what it seems to me is that  
24 under the regulation, as new information or new analysis  
25 reveals additional concerns, the company has a unilateral

1 opportunity to change it. And so if you can demonstrate  
2 through your evidence that they had a new analysis of the  
3 existing RE-LY data that should have supported them making the  
4 change in the label, then you can hold them accountable for  
5 failing to change the label until they did or in the way that  
6 they did.

7 But it still seems to me that it starts with the label  
8 that you've been attacking from the beginning as deficient  
9 with regard to the 75-milligram dose for the two reasons that  
10 I've said. And those are two reasons that, it seems to me,  
11 the FDA clearly contemplated when they granted approval.

12 MR. CHILDERS: And, Your Honor, if I could.

13 THE COURT: Yes.

14 MR. CHILDERS: There was a label change between the  
15 launch label and the time she started the drug.

16 THE COURT: Okay.

17 MR. CHILDERS: That's the label we are attacking  
18 because that's the label that was in effect at the time. It's  
19 not the launch label.

20 The reason we're seeing the launch label is because  
21 the one in effect at the time she started it, for whatever  
22 reason, doesn't have a Medication Guide attached to it, so we  
23 have to use the Medication Guide that came from the launch  
24 label. It's very strange, I know.

25 THE COURT: Well, and, you know, we've got --

1 unfortunately for your side, I think that there was a good  
2 argument from the defendant that the regulations preclude the  
3 defendant's unilateral alteration of the Medication Guide.

4 MR. CHILDERS: Understood.

5 THE COURT: And because of that, under Wyeth and the  
6 other cases, they can't be faulted for failure to change the  
7 Medication Guide.

8 MR. CHILDERS: And I'm not trying to argue that, Your  
9 Honor.

10 THE COURT: I know that.

11 MR. CHILDERS: I'm just explaining to you the reason  
12 why you keep seeing the launch label. There's just not a  
13 Medication Guide attached to the March 2011 label, so we can't  
14 hand it to a witness and say turn to the medication label  
15 because it's just not there.

16 THE COURT: Okay. And my response to that really is  
17 so what?

18 If the label that was approved originally or the first  
19 one that was -- the one that was still in effect when she got  
20 her prescription proposed or allowed for the 75-milligram  
21 dose, it was allowed based upon the FDA's decision that we are  
22 allowing -- in fact, they directed it or suggested it. I  
23 realize in negotiation maybe they put them up to it. But the  
24 FDA approved that dose from the beginning knowing that the  
25 study, the RE-LY study did not include severely impaired renal

1 patients, and that's been one of your criticisms of the  
2 75-milligram dose. And the second criticism of it has been  
3 that it was modeling based rather than clinical trial based.  
4 The FDA knew that as well.

5 So I don't see how I can avoid finding that, to the  
6 extent that any of the label from the first one through the  
7 time she took it had the 75-milligram dose, it strikes me that  
8 it was -- that any claim that that label is deficient for that  
9 patient group, the 75-milligram dose for those two reasons is  
10 preempted.

11 MR. MOSKOW: Your Honor, may I?

12 THE COURT: Yes.

13 MR. MOSKOW: Thank you, Your Honor.

14 Let me start by saying that I realize that because of  
15 the way this motion was raised, we're all kind of scrambling,  
16 so I need to take a step back.

17 Which is that impossibility preemption, which is the  
18 claim they've raised here, is not that the FDA didn't --  
19 didn't know something and acted in a way that we believe is  
20 improper. Impossibility preemption reflects the sponsor, the  
21 drug company's obligation to craft an adequate label and make  
22 sure that it's accurate at all times.

23 And where impossibility comes in is if they identify  
24 something in the label that is inaccurate or incomplete, or  
25 because of either new analysis or new information determine

1 that it needs to be changed, they have the ability under the  
2 CBE process to do that.

3 What we're -- what we've identified as failings here  
4 is that, as the product was being marketed -- actually on  
5 cross-examination of Dr. Plunkett, they actually put into  
6 evidence FDA notices of additional reports of adverse -- you  
7 know, adverse events.

8 THE COURT: Right.

9 MR. MOSKOW: They put in information about the  
10 75-milligram dose being used in the Graham study, for example.  
11 So as this information is becoming available, they learned,  
12 you know what, prescribers need to know additional  
13 information. And to meet their burden on impossibility, they  
14 have to show that they actually proposed the labeling changes  
15 that we're talking about, and they were rejected. Or that,  
16 based on FDA action, that the labeling change would not have  
17 been -- would not -- it is a very high burden, by clear and  
18 convincing evidence.

19 THE COURT: So why can they not establish that by the  
20 evidence that demonstrates that at the time the FDA approved  
21 this, they knew, well knew two obvious facts about this study.  
22 One, that patients who were severely impaired renally were not  
23 part of the study. The FDA knows that. Maybe through further  
24 analysis it becomes clearer and so forth, but that is not what  
25 you're claiming.

1           You're claiming that they should have been -- that  
2           from the time the FDA approved a label, that label should have  
3           said severely impaired renal patients weren't part of the  
4           study, and we used modeling rather than clinical trials --

5           MR. MOSKOW: Right.

6           THE COURT: -- for that 75 dose.

7           MR. MOSKOW: There are two reasons, Judge.

8           The first is because it's not FDA's knowledge that is  
9           at issue in impossibility preemption. It is whether the FDA  
10          would have approved a label change had one been made under the  
11          CBE process. And in this case, there is no -- they have not  
12          met their burden of showing that it would not have been  
13          approved. That's the first thing.

14          And the reason we know that is true is because the  
15          same data from the RE-LY trial, upon which they approved the  
16          drug, is the data that has been reanalyzed to reflect, ah,  
17          this increase in bleed risk with no concomitant improvement in  
18          stroke reduction. And that is information that isn't in the  
19          label.

20          So the data -- it's the same data set, but the  
21          information that is drawn from it, what is being done in the  
22          marketplace, how physicians are responding to it is that new  
23          analysis.

24          THE COURT: Well, I agree there was obviously new  
25          analysis and, as a result, they exercised their authority,

1 that BI exercised its authority to unilaterally through the  
2 CBE process change the label, strengthen warnings, restated  
3 them, improved upon them greatly. But, you know, I'm having  
4 trouble saying that the two grounds that you've asserted as  
5 the reasons the 75 dose was improper from the beginning were  
6 somehow not before the FDA. I mean, I think they were.

7 MR. MOSKOW: So, Your Honor, maybe we're just  
8 miscommunicating. Let me try again.

9 THE COURT: Yes.

10 MR. MOSKOW: And I'm sure it is because there are two  
11 of us here trying to figure out the best way to say it.

12 THE COURT: It can't be my fault, we know that.

13 MR. MOSKOW: We know that.

14 So we're not arguing that the dose should not have  
15 been approved. We're not arguing that the dose may not be  
16 appropriate for a particular class of patients.

17 THE COURT: Right.

18 MR. MOSKOW: What we're saying is that there is  
19 information about the lack of testing, both of the dose itself  
20 and in severe renal -- in any of the people in the RE-LY  
21 study --

22 THE COURT: Right.

23 MR. MOSKOW: -- that should have been communicated.

24 No doubt the FDA knew that. But it's incumbent upon  
25 the defendant to demonstrate that it sought to include that

1 information in the label, and the FDA said no, or would have  
2 said no based on the totality of the circumstances. And there  
3 is no evidence of that and, in fact, it's exactly the  
4 contrary.

5 As Mr. Childers just demonstrated, they added that  
6 information to the label in Exhibit 86. It's not there in  
7 Exhibit 87. In 88, it is there. So rather than being  
8 impossible, when they sought to add that information, they  
9 were able to do so.

10 I think we're confusing what the FDA knew at the time  
11 of approval versus Boehringer's obligation to ensure that the  
12 label was adequate at all times.

13 THE COURT: Okay.

14 MR. MOSKOW: And I --

15 THE COURT: Well, let me hear the defense side of  
16 this, and then I want to get back to these instructions.  
17 We'll finish this up, and I'll continue thinking about it.

18 MR. LEWIS: Your Honor, you have the analysis correct,  
19 so I'm going to start there.

20 The statement of law that Mr. Moskow made is  
21 unfortunately incorrect. The way this works, and this is the  
22 conflict preemption analysis, it starts with the proposition  
23 that you have an FDA-approved label. And there are certain  
24 things that permit a manufacturer to change the label, certain  
25 things, and those certain things are contained in changes



1 being effected. And the things that allow someone to change  
2 the label are newly acquired information on a particular topic  
3 or a new analysis as the courts have kind of expounded upon.

4 But that has to be present in order to change the  
5 label. Manufacturers cannot just willy-nilly change the label  
6 without a new analysis or new data to support the change. It  
7 just can't happen. It is not permissible, and that is the  
8 conflict here in this case.

9 Because the two things -- and each of these claims  
10 does have to be run through a preemption analysis. The two  
11 things that are being complained about by the plaintiffs here  
12 are, as Your Honor stated, the fact that it wasn't tested on  
13 the 75-milligram dose. That's a fact that was in existence at  
14 the time the FDA label was approved, and there was never a new  
15 analysis to suggest anything other than we didn't test the 75  
16 milligrams. And the same goes through with the renal -- renal  
17 impairment.

18 The change that was made was about the level of the  
19 increase in risk. But the fact of whether we tested the  
20 75-milligram dose or the fact of whether we tested on severely  
21 renally impaired patients never changed, and there was no new  
22 analyses on those two facts to change anything that the FDA  
23 knew or the company knew at the time that the original label  
24 was approved.

25 So on those two points, Your Honor, the Court is

1 correct in its analysis.

2 THE COURT: Okay.

3 MR. CHILDERS: May I just say one thing, Your Honor?  
4 I guess this is where I am really having confusion.

5 They actually made a CBE change to say exactly what we  
6 asked -- are saying that they should change. So I'm unclear  
7 how that could possibly be impossible for them to do because  
8 they did it through the CBE process.

9 THE COURT: I don't know that -- you may be right. I  
10 don't know that I would say that it's impossible. But  
11 thinking in terms of conflict preemption, what I see is the  
12 FDA explicitly approving the dose knowing the two facts from  
13 the time of its approval that you claim now should have  
14 resulted in some new or different warning.

15 And so I'll go back --

16 MR. CHILDERS: Can we possibly put something together  
17 and -- I think we're just having a hard time communicating.

18 THE COURT: Could be.

19 MR. CHILDERS: The issue is that, ah, my understanding  
20 again of preemption is that you have to show that they are not  
21 able to make this change on their own. They have to have some  
22 FDA assistance in order to do it.

23 THE COURT: FDA approval.

24 MR. CHILDERS: Correct. They did it without FDA  
25 approval is what I'm pointing out.

1 THE COURT: I understand.

2 MR. CHILDERS: So if we could -- thank you, Your  
3 Honor.

4 THE COURT: All right. Well, so at least for now,  
5 then, I guess there's no need to try to resolve this  
6 instruction. It's going to be tied to the discussion we just  
7 had.

8 Then going on, I'm now on page 15 of my proposed  
9 instructions. There is the foreign labeling limiting  
10 instruction. We've already said there is the failure to test  
11 and the issue we just talked about.

12 On the next page, on page 16, I've included the  
13 defendant's request for an instruction that BI has a duty to  
14 provide warnings, but because it's a prescription, you can  
15 consider the information BI provided to doctors.

16 Do plaintiffs object to that instruction?

17 MR. MOSKOW: We did, Your Honor. I believe it's some  
18 evidence --

19 THE COURT: Well --

20 MR. MOSKOW: Maybe if we add --

21 THE COURT: -- all it says here is you may consider  
22 it. So --

23 MR. MOSKOW: We think it's superfluous, Your Honor, so  
24 we would maintain our objection. We understand the Court's  
25 position.

1 THE COURT: Well, what do you mean superfluous?

2 MR. MOSKOW: Because they're being told that they  
3 should, in an earlier instruction, consider all evidence,  
4 direct and circumstantial.

5 And to the extent that there is evidence they can  
6 infer that the information got from the physician to the --

7 THE COURT: Okay.

8 MR. CHILDERS: I think that was our issue, Judge.  
9 This is calling out one specific piece of evidence as opposed  
10 to just telling them they should consider all of the evidence,  
11 and that was the objection I thought that we had made  
12 previously.

13 THE COURT: Well, I'm happy to add a phrase if you  
14 think that would provide the balance, to make reference to the  
15 other sources of information.

16 MS. JONES: Your Honor, I don't want to run us into  
17 another preemption buzz saw, but I think this may also raise a  
18 question about just needing to get an understanding of the  
19 rules of the road on the Medication Guide preemption issues.

20 Because as we've made clear, and Your Honor has  
21 mentioned, we think that because the regulations don't permit  
22 a change in that Medication Guide, they should not be able to  
23 make arguments about whether the Medication Guide was adequate  
24 or inadequate for any reason.

25 THE COURT: Well, and I've tried to say that, and I

1 said I'd entertain an instruction that more explicitly says  
2 that plaintiff may not assert as a theory of failure to warn a  
3 different Medication Guide. Plaintiff has introduced evidence  
4 about what is in the guide and what's not. What's in the  
5 guide is information that goes to patients, and clearly that  
6 is admissible evidence. What is not may also go to a  
7 patient's knowledge, and it also goes to the defendant's  
8 knowledge. When you put things in the Medication Guide, you  
9 know about them, BI does.

10 So I think either way it's still -- it's evidence of  
11 what warnings or instructions were available, and yet we're  
12 telling the jury, properly I think, that they can't have --  
13 they can't find for plaintiffs on the basis that the  
14 Medication Guide should have been rewritten so that it  
15 disclosed those things.

16 MS. JONES: Understood, Your Honor. And we have put  
17 together a draft of a proposed instruction, which we're happy  
18 to submit.

19 THE COURT: Okay.

20 MS. JONES: I guess more broadly, we also want to be  
21 sure that we're clear that counsel will not stand up in front  
22 of the jury and point at the Medication Guide and say it  
23 didn't have these five things that we've seen rolled out so  
24 many times. That would be concerning for us.

25 THE COURT: Well, you know, I can't stop them from

1 standing up and saying here's a piece -- here's a document  
2 that is in evidence, here's what it says, here's what it  
3 doesn't say.

4 I understand your concern. I think they can't argue  
5 that the failure of the Medication Guide to say these things  
6 is enough for the jury to find a failure to warn has been  
7 proven.

8 Compliance with safety standards, I think we added the  
9 so-called mirror language that we talked about?

10 MR. MOSKOW: Yes, Your Honor.

11 MS. JONES: And we would maintain our objection to  
12 that addition, Your Honor. We don't think there has been any  
13 evidence of the company not complying with appropriate  
14 regulations, and so we think that instruction is  
15 inappropriate.

16 THE COURT: Well, I want to hear more about that when  
17 we get to this point.

18 I've been trying to go back and reread some of  
19 Plunkett's testimony, and I've gotten about halfway through  
20 it. And she's asked about regulations, but only as the  
21 structure for her approach and analysis, not -- so far from  
22 what I've read, not a claim by her that there was a regulation  
23 that was violated.

24 I guess it's going to come down to, as I think maybe  
25 you argued on the plaintiffs' side, that the regulation says

1 you gotta be truthful and complete or something to that  
2 effect, and I'm trying to figure out if that's what you're  
3 talking about.

4 MR. MOSKOW: It is, Your Honor.

5 THE COURT: Okay.

6 MR. MOSKOW: Under I believe it's 314.8. I could be  
7 off slightly. But 21 CFR specifically requires the company to  
8 be complete, balanced and accurate in its labeling.

9 And the testimony from Dr. Plunkett is that it was  
10 incomplete, and that it lacked critical information, and we  
11 believe that that is competent evidence of a failure to comply  
12 with regulation.

13 MS. JONES: And we agree that she said the labeling  
14 didn't include certain things. That's very different in our  
15 minds from saying you violated a federal regulation. That is  
16 a very specific criticism, which frankly we think raises  
17 another preemption issue. But, in any event, she didn't say  
18 that when she testified.

19 MR. MOSKOW: And there's no evidence that they have  
20 complied with any specific regulation either, Your Honor,  
21 which is --

22 THE COURT: Well, I'm going to continue reviewing her  
23 testimony.

24 The next one was on page 18, the treatise instruction  
25 that I thought nobody objected to.

1           Then on 12, we get into strict liability. I think  
2           there was no objection on 12, what I believe was 12 on 13.

3           On 14, I know that the defendant objected to the final  
4           paragraph which plaintiffs wanted inserted based on the Wyeth  
5           case. I've included the language. You can more fully state  
6           your reason for objecting to document the record. Maybe I'll  
7           change my mind, I don't know. But at least you'll have your  
8           chance when we go through these tomorrow to formally state  
9           your objection.

10           Next on 15 starts the negligence under duty to warn.  
11           I don't think there was any significant objection to that.

12           I'm trying to find --

13           MR. CHILDERS: My notes said that that same language  
14           was going to be added here from Wyeth and the Johnson case?

15           MS. JONES: That is consistent with what I had  
16           scribbled down, Your Honor, that that is a parallel addition.  
17           I mean, we reserve our objection obviously, but I think that's  
18           what we had talked about last week.

19           THE COURT: Well, I missed that. So what language?

20           MR. CHILDERS: So that same language, Your Honor, that  
21           was added to the last paragraph, the last two paragraphs you  
22           just mentioned on 14, instruction 14, strict liability failure  
23           to warn.

24           THE COURT: Oh. The it is --

25           MR. CHILDERS: Starting with Boehringer as a



1 manufacturer of prescription drugs --

2 THE COURT: All right.

3 MR. CHILDERS: -- and then all the way through to the  
4 end.

5 THE COURT: Okay. So plaintiffs submit that should be  
6 repeated in the negligence claim as well?

7 MR. CHILDERS: Right. And I believe in the conference  
8 we had last week, everybody agreed that if it went into one,  
9 it should go into the other.

10 THE COURT: All right. I'll add that. I know the  
11 defendant objects to it, and we'll hear you further tomorrow.

12 All right. 16, the standard of care.

13 17, a causation warning definition. The defendant had  
14 a sentence proposed in theirs at the end that said: Further,  
15 if plaintiffs did not prove that Pradaxa caused death, you  
16 must find -- you may find in favor of BI.

17 To me, that was just inconsistent with the rest of and  
18 the purpose of --

19 MS. JONES: That's fine.

20 THE COURT: -- that instruction.

21 MS. JONES: That's fine, Your Honor.

22 THE COURT: So I took it out.

23 MS. JONES: Yes.

24 MR. CHILDERS: Your Honor, the last sentence in this  
25 particular instruction is: If plaintiffs did not prove it is

1 more likely than not that Ms. Knight read the warnings  
2 provided by BI, they cannot prove that different warnings  
3 would have caused her to change her behavior.

4 I'm not -- that seems to be a little different than  
5 the evidence that has come in because what we've established  
6 is there was a lot of information that was not provided to  
7 Mrs. Knight in particular.

8 And I understand that the Medication Guide can't be  
9 changed, but what we have is testimony today that there was no  
10 other communication that Dr. Shami was aware of -- I don't  
11 know if Dr. Crossley will have a different opinion -- in which  
12 the information was provided.

13 So I --

14 THE COURT: So what are your theories about how the  
15 information -- where and how it should have been provided that  
16 it could have made a difference in her decision to take  
17 Pradaxa?

18 MR. CHILDERS: So under the law, they can -- they can  
19 direct-to-consumer communicate through television ads,  
20 magazine ads, letters if they choose to do it. They can send  
21 out mailers with coupons in it to patients. As long as the  
22 information they include is in the label, they're allowed to  
23 communicate that.

24 And so I think what we have here is -- I just don't  
25 want to get in a situation where the jury says, well, she

1 didn't -- maybe what they decide is she didn't read the  
2 Medication Guide, which we are not relying on to say they  
3 didn't warn.

4 THE COURT: Right.

5 MR. CHILDERS: But, rather, she just never got  
6 anything else to read, and if she didn't get it to read, then  
7 this says you can't find in the plaintiffs' favor. And that's  
8 how I read that last sentence, Your Honor.

9 MS. JONES: A couple responses, Your Honor.

10 The first is, you know, this theory about, well, they  
11 can advertise by television and magazine, and they can send  
12 things to people's homes -- which I'm not entirely sure is  
13 even accurate and is kind of a late-breaking theory of the  
14 facts of the case. But the other point, which is more  
15 important I think, is that this statement at the conclusion of  
16 this causation instruction is black letter warnings causation  
17 law. It's referenced at various points in the citations that  
18 we provided.

19 And even if you embrace their theory that there were  
20 other mechanisms by which the company could have provided  
21 information to Mrs. Knight, the bottom line is she has to have  
22 seen those warnings and looked at them and made a decision  
23 based on them for that to matter for purposes of causation. I  
24 don't think there's any question about that basic legal  
25 principle, whatever the mechanism of communicating the

1 information.

2 THE COURT: Yeah, this is a confusing one to me.

3 So perhaps you can explain where in the testimony you  
4 have evidence that something other than what -- we've talked  
5 about the Medication Guide. We seem to be in agreement there.  
6 Obviously the label is the other primary source that was  
7 provided to her.

8 What is the evidence that you've adduced about the  
9 duty for BI to convey warnings through some other means?

10 MR. CHILDERS: Well, Your Honor, I think the law in  
11 West Virginia is you have to provide warnings directly to the  
12 patient, and what Dr. Plunkett testified about are the means  
13 available to a company to provide information directly to  
14 patients.

15 Advertising is one on television, again print  
16 advertising, and drug companies do send out mail. I myself  
17 have received it before. Here's a coupon for whatever, if you  
18 want to go in and fill it, you got \$5 off.

19 And I can't remember everything --

20 THE COURT: A dear doctor letter she said?

21 MR. CHILDERS: Yes, sir.

22 THE COURT: Did she testify specifically about are  
23 there regulations or --

24 MR. CHILDERS: Sure.

25 THE COURT: -- standards that apply to dear doctor

1 letters?

2 MR. CHILDERS: There are, Your Honor. They have to --  
3 they can't communicate anything that is not in the label.  
4 That's basically what it comes down to, and that is also with  
5 television ads.

6 And so with television ads, how that works, the  
7 company puts it on the air, and they send a copy of it to the  
8 FDA. And the FDA later looks at it and either says nothing or  
9 they say you shouldn't have aired that, so don't do it again.  
10 So it's not one of those situations where they have to get  
11 approval to do anything.

12 THE COURT: So here the only evidence about anybody  
13 seeing a TV ad was daughter Claudia saying she thought she saw  
14 an ad for Pradaxa.

15 MR. CHILDERS: Correct.

16 THE COURT: Okay. So you don't even have evidence  
17 that Betty Knight saw any advertising for anything. So if  
18 Betty Knight -- if there isn't evidence that Betty Knight saw  
19 advertising, then how is that any different from these cases  
20 where the patient didn't see things, didn't read the label  
21 and, therefore, was determined that, as a matter of law, the  
22 warning wouldn't have mattered?

23 MR. CHILDERS: Well, I think the case in particular,  
24 the Zyprexa case that is cited here, first of all, was a  
25 summary judgment issue. And second of all, the testimony was

1 they did not read the label.

2 We have --

3 THE COURT: Right.

4 MR. CHILDERS: We have testimony here that Betty  
5 Knight received information, she saved it, she looked at it.  
6 And so I don't think obviously summary judgment or directed  
7 verdict would be appropriate, which is what this is talking  
8 about.

9 THE COURT: Right, I agree.

10 So that's why I thought that what the jury should be  
11 asked to determine is whether they find Betty Knight read the  
12 label, more likely than not read the label. Because then, if  
13 an adequate label had been included with the prescription any  
14 of the times she got it, arguably she would have changed her  
15 behavior and not stayed on -- not started taking Pradaxa or  
16 stayed on it.

17 MR. CHILDERS: Yes, sir.

18 THE COURT: So --

19 MR. CHILDERS: I'm sorry.

20 THE COURT: Well, I'm --

21 MR. CHILDERS: Understood.

22 The only other issue I guess we would have is the  
23 testimony that has come in, is this was a decision made by the  
24 three family members. And so the two children were actually  
25 the ones who suggested let's go do this. And the testimony we

1 have, since Betty Knight is deceased, is this is what the  
2 children knew when they made this request.

3 So at least we would ask that it say that Ms. Knight  
4 or her family. Or Rick or Claudia or however -- or  
5 plaintiffs. How about that, that plaintiffs read the warning,  
6 because that would include Betty Knight as well.

7 But that's the testimony that has come through the  
8 trial is that this was a decision the three of them made  
9 together where they sort of pushed it instead of it being a  
10 doctor recommendation that Betty Knight considered on her own.

11 MS. JONES: Your Honor, if I could respond briefly.

12 First of all, the law is that our obligation, the  
13 company's obligation was to Mrs. Knight. There was not a  
14 complimentary obligation to her children who might have been  
15 involved with her medical care. That's not what the legal  
16 principle is, first of all.

17 Second of all, there was no testimony from either  
18 Ms. Stevens or from Mr. Knight that either of them ever saw  
19 the Medication Guide or read the Medication Guide. So even if  
20 you group them all into the same pot of people, the analysis  
21 is still the same. The instruction is still appropriate.

22 Thirdly, we have now heard more about this  
23 advertisement. The advertisement is not in evidence. All we  
24 have is what I think Ms. Stevens testified to in terms of what  
25 she saw, but there has never been any criticism of a specific

1 advertisement. Dr. Plunkett didn't say I've looked at the  
2 advertisement for Pradaxa, and I deem it to be inadequate for  
3 some reason. That's been a peripheral issue at best.

4 So we think the instruction is black letter causation  
5 law in these types of cases. We don't think it's appropriate  
6 to be grouping together the members of the family as though  
7 there was an obligation that extended beyond Mrs. Knight.

8 MR. CHILDERS: You probably don't want to hear me say  
9 anything --

10 THE COURT: What?

11 MR. CHILDERS: You probably don't want to hear me say  
12 anything else.

13 THE COURT: Sure, go ahead. Go ahead.

14 MR. CHILDERS: I think I've said everything, Your  
15 Honor.

16 THE COURT: Well, I understand some of your points.  
17 I'm struggling with it, though. I agree with what Ms. Jones  
18 said.

19 Part of the problem here is it sounds like we are  
20 starting to instruct the jury that the duty is to inform the  
21 family of the appropriate warnings about a medication. You  
22 know that ain't going to last long if it goes up on  
23 something -- a favorable verdict.

24 I see what your point is about, that here there is  
25 evidence that the family participated in the decision. They



1 were the ones who started the process. And obviously they  
2 testified they at least implicitly talked to her about it,  
3 they all agreed to talk to the doctor about it, and they all  
4 talked to the doctor about it.

5 But I think that the obligation owed to Mrs. Knight,  
6 and the corresponding duty that the cases talk about is that  
7 the purchaser has to avail themselves of the manufacturer's  
8 warnings or can't fault the warnings for being inadequate.  
9 And so I think I'm probably likely to stick with the language,  
10 and you can argue about whether the family would have  
11 encouraged her to make a different decision.

12 MR. CHILDERS: Understood, Your Honor.

13 THE COURT: Okay. The next instruction is 18, express  
14 warranty. Now, I know that in the preliminary instructions  
15 the Court included, as proposed by the plaintiffs, the  
16 statement that BI made a statement of fact to Mrs. Knight,  
17 something to the effect that Pradaxa was safe and effective  
18 for her. I don't get that as being sufficient in an express  
19 warranty case. I think you've got -- for express warranty,  
20 you've got to show an actual statement in the label that was  
21 either misleading or false.

22 If you are arguing, and I'm sure you are, that a  
23 manufacturer who puts the product into the -- gets FDA  
24 approval and puts the product into the market is representing  
25 that it is a safe and effective drug, well, clearly that is

1 the case, but that is an implied warranty, it seems to me.

2 And so I think you've got to be able to show, for violation of  
3 an express warranty, that a specific statement was misleading  
4 or inaccurate or perhaps even omitted. But I don't think you  
5 can just say there is an express warranty that this is safe  
6 and effective for Betty.

7 So I leave the language there as a statement of fact  
8 to Mrs. Knight related to Pradaxa. I --

9 MR. CHILDERS: That's what I understood from the  
10 conference, Your Honor. We don't have anything to add to  
11 that.

12 MS. JONES: The only -- I think just a corresponding  
13 change, Your Honor, in light of that, is on the second line of  
14 the instruction. It says: Mrs. Knight was injured by Pradaxa  
15 because BI represented that Pradaxa was safe. I think that  
16 probably should be edited to say: Plaintiffs claim that  
17 Mrs. Knight was injured by Pradaxa because Pradaxa was not as  
18 represented.

19 MR. CHILDERS: That's fine, Your Honor.

20 THE COURT: Well, say that language again so we can  
21 get it. Because I don't have that in my notes from --

22 MS. JONES: We had -- I don't think we had discussed  
23 this first section. I think we had just talked about the  
24 specific element in element 3. But it occurred to me when I  
25 was looking through the draft earlier today that we would need

1 to make a corresponding change in the second line.

2 THE COURT: Okay. So tell me again what you want to  
3 add and where.

4 MS. JONES: It's not an add, it's a deletion.

5 So the second sentence starts with plaintiffs claim.  
6 I think it should now say: Plaintiffs claim Mrs. Knight was  
7 injured by Pradaxa because, and then say Pradaxa was not as  
8 represented. So it's just cutting out those intervening  
9 words.

10 THE COURT: Oh, I see. Okay.

11 (Off-the-record discussion with law clerk.)

12 THE COURT: Okay. We'll change that.

13 On the next page is the implied warranty. I don't  
14 recall there being -- well, I take that back.

15 There was some discussion about this, and --

16 MR. MOSKOW: You made the change on line 3, Your  
17 Honor, that we had discussed.

18 THE COURT: Right. That is essentially quoting the  
19 statute.

20 MR. MOSKOW: Right.

21 MS. JONES: That's consistent with my recollection,  
22 Your Honor.

23 THE COURT: All right. So -- all right.

24 And then the next is on page 27, the fraud claim. I  
25 thought the parties were in agreement on that.

1           Then we get into the wrongful death instruction. I  
2           thought the parties were in agreement there.

3           MR. MOSKOW: Yes, Your Honor.

4           MS. JONES: Yes, Your Honor.

5           THE COURT: All right. So that brings us to the  
6           punitive damages, which the parties had not had a chance to I  
7           guess either discuss or at least didn't get a chance to convey  
8           your positions to me. So I'm going to set those aside again  
9           for the moment.

10          Then if you keep going, at page 37 I've included the  
11          plaintiffs' request to instruct on Betty's preexisting  
12          condition. And I've included plaintiffs' request on  
13          concurrent negligence.

14          MS. JONES: And we did have an objection to that one,  
15          Your Honor, which we discussed last week.

16          THE COURT: Right. And we can discuss that, and you  
17          can argue about it before.

18          So that pretty much covers everything that I had.

19          Do you know -- I asked Blake to just look at the West  
20          Virginia pattern instructions on punitive damages, and he and  
21          I have had barely a minute to talk about it, but it seemed  
22          that these were pretty much out of those.

23          MR. CHILDERS: That's what we proposed, Your Honor.  
24          They had proposed some additional ones, and we objected to  
25          anything beyond the pattern.

1 MS. JONES: That is the state of things, yes.

2 THE COURT: All right. Well, at least that gives me a  
3 little more focus of what to look at. So I'll look at the  
4 additional instructions the defendant seeks.

5 So is there anything else, then, about these  
6 instructions that you want to discuss now?

7 MR. CHILDERS: So I can be clear, we're going to go  
8 over them in another conference tomorrow?

9 THE COURT: Yes, absolutely.

10 MR. CHILDERS: Okay. Thank you, Your Honor.

11 THE COURT: And so to facilitate things, obviously  
12 between now and as soon tomorrow as you can get to it, if you  
13 would provide any new or proposed changes or additions in  
14 writing, it would be great. Exchange it and provide it to me.

15 What I would hope to do is, as I said, at the latest  
16 tomorrow evening after we excuse the witness at whatever time,  
17 stay and have a formal charge conference where we will go  
18 through these again, letting each side identify anything that  
19 they object to that's in my draft, and the defense can object  
20 to anything, whether it's an omission or you want to delete  
21 something. We will do it on the record then and be finished  
22 by tomorrow evening so we're ready to instruct this jury as  
23 soon as we can on Wednesday.

24 Okay?

25 MR. CHILDERS: Thank you, Judge.

1 MR. MOSKOW: Thank you, Judge.

2 THE COURT: All right. See you tomorrow.

3 THE COURT SECURITY OFFICER: All rise. This court is  
4 now in recess.

5 (Proceedings were adjourned at 6:44 p.m.)

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1 CERTIFICATION:

2 We, Kathy L. Swinhart, CSR, and Lisa A. Cook,  
3 RPR-RMR-CRR-FCRR, certify that the foregoing is a correct  
4 transcript from the record of proceedings in the  
5 above-entitled matter as reported on October 15, 2018.

6  
7  
8 October 16, 2018  
9 DATE

10 /s/ Kathy L. Swinhart  
11 KATHY L. SWINHART, CSR

12 /s/ Lisa A. Cook  
13 LISA A. COOK, RPR-RMR-CRR-FCRR  
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